

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)
) CR-18-00258-EJD
 PLAINTIFF,)
) SAN JOSE, CALIFORNIA
 VS.)
) AUGUST 20, 2021
 ELIZABETH A. HOLMES,)
) PAGES 1 - 82
 DEFENDANT.)
 _____)

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTER:

IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

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A P P E A R A N C E S: (CONT'D)

FOR DEFENDANT HOLMES: WILLIAMS & CONNOLLY LLP
BY: KEVIN M. DOWNEY
LANCE A. WADE
PATRICK LOOBY
KATHERINE TREFZ
AMY SAHARIA
725 TWELFTH STREET, N.W.
WASHINGTON, D.C. 20005

1 SAN JOSE, CALIFORNIA

AUGUST 20, 2021

2 P R O C E E D I N G S

10:08AM 3 (COURT CONVENED AT 10:08 A.M.)

10:08AM 4 THE COURT: LET'S GO ON THE RECORD IN OUR MORNING
10:08AM 5 MATTER. THIS IS 18-258, UNITED STATES VERSUS ELIZABETH HOLMES.
10:08AM 6 LET ME FIRST CAPTURE THE APPEARANCES OF THE PARTIES,
10:08AM 7 PLEASE.

10:08AM 8 WHO APPEARS FOR THE GOVERNMENT?

10:08AM 9 MS. VOLKAR: GOOD MORNING, YOUR HONOR.

10:09AM 10 KELLY VOLKAR ON BEHALF OF THE GOVERNMENT, THE UNITED
10:09AM 11 STATES OF AMERICA, AND ALONG WITH ME AT COUNSEL TABLE ARE MY
10:09AM 12 COLLEAGUES: ROBERT LEACH, JEFF SCHENK, JOHN BOSTIC, AND OUR
10:09AM 13 SPECIAL CASE ADELAIDA HERNANDEZ.

10:09AM 14 THE COURT: THANK YOU. GOOD MORNING.

10:09AM 15 WHO APPEARS FOR THE DEFENDANT?

10:09AM 16 MR. WADE: GOOD MORNING, YOUR HONOR.

10:09AM 17 LANCE WADE FROM WILLIAMS & CONNOLLY ON BEHALF OF
10:09AM 18 MS. HOLMES, WHO IS PRESENT HERE IN THE COURTROOM TODAY.

10:09AM 19 THE COURT: THANK YOU. GOOD MORNING.

10:09AM 20 MR. WADE: ALSO PRESENT WITH ME TODAY ARE
10:09AM 21 MR. DOWNEY, MR. LOOBY, MS. TREFZ, AND MS. SAHARIA.

10:09AM 22 THE COURT: GOOD MORNING.

10:09AM 23 THIS IS THE DATE AND TIME SET FOR SOME DISCUSSION ON SOME
10:09AM 24 MOTIONS FILED BY MS. HOLMES. THESE ARE, LET'S SEE, DOCKETS --
10:09AM 25 I BELIEVE IT'S 892, 895, 897, AND 899.

10:09AM 1 AND I HAVE RECEIVED YOUR PLEADINGS, THE REPLIES. THANK
10:09AM 2 YOU FOR THOSE.

10:09AM 3 I THOUGHT I WOULD LIKE TO GO THROUGH THOSE -- THESE WITH
10:10AM 4 STARTING WITH THE 895 I THINK IT IS. THIS IS A MOTION TO
10:10AM 5 EXCLUDE CERTAIN NEWS ARTICLES.

10:10AM 6 MR. LOOBY, ARE YOU RISING TO THAT?

10:10AM 7 MR. LOOBY: YES. GOOD MORNING, YOUR HONOR.

10:10AM 8 I'LL BE ADDRESSING THIS MOTION.

10:10AM 9 THE COURT: WHAT WOULD YOU LIKE ME TO KNOW IN
10:10AM 10 ADDITION TO WHAT YOU'VE TOLD US IN YOUR PLEADINGS?

10:10AM 11 MR. LOOBY: SO THANK YOU, YOUR HONOR.

10:10AM 12 I THINK I CAN BE BRIEF.

10:10AM 13 THE COURT: THAT'S ALWAYS GOOD, MR. LOOBY.

10:10AM 14 MR. LOOBY: YES.

10:10AM 15 AND THE REASON FOR THAT IS THAT THIS IS KIND OF A
10:10AM 16 STRAIGHTFORWARD PRETRIAL CLEAN-UP MOTION. THE SEVEN ARTICLES
10:10AM 17 ATTACHED TO THE MOTION WE SUBMIT WOULD HAVE BEEN EXCLUDED UNDER
10:10AM 18 THE COURT'S ANALYSIS IN ITS MAY IN LIMINE ORDER.

10:10AM 19 IF YOU LOOK AT THE ARTICLES, THEY EACH CONTAIN REPORTING
10:10AM 20 THE PARROTS "THE WALL STREET JOURNAL" REPORTING, AND OTHER
10:10AM 21 CRITICAL COVERAGE OF THERANOS, INVESTIGATORY PIECES THAT THE
10:10AM 22 GOVERNMENT HAS PROPOSED TO OFFER TO PROVIDE CONTEXT FOR
10:11AM 23 MS. HOLMES AND THE COMPANY'S RESPONSE.

10:11AM 24 THE COURT CORRECTLY HELD AND SAID THIS PURPOSE RELIES ON
10:11AM 25 THE TRUTH OF THE ARTICLES FOR ITS RELEVANCE AND SO THEY MUST BE

10:11AM 1 EXCLUDED. THE GOVERNMENT'S OPPOSITION POSITS NO OTHER PURPOSE
10:11AM 2 FOR THESE ARTICLES.

10:11AM 3 SO THE COURT NEED NOT WAIT TO EXCLUDE THEM NOW ON HEARSAY
10:11AM 4 GROUNDS. AND IF THERE WERE ANY RESERVATION ON THAT POINT, THEN
10:11AM 5 RULE 403 WOULD PROVIDE AN ALTERNATIVE BASIS.

10:11AM 6 SO UNLESS YOUR HONOR HAS ANY SPECIFIC QUESTIONS ABOUT THE
10:11AM 7 ARTICLES?

10:11AM 8 THE COURT: WELL, I DO HAVE SOME.

10:11AM 9 DO THESE ARTICLES CONTAIN WHAT YOU WOULD DESCRIBE AS
10:11AM 10 ADMISSIONS THAT WOULD OTHERWISE BE ADMISSIBLE?

10:11AM 11 MR. LOOBY: I DON'T BELIEVE SO, YOUR HONOR. SOME OF
10:11AM 12 THEM PURPORT TO QUOTE MS. HOLMES --

10:11AM 13 THE COURT: RIGHT.

10:11AM 14 MR. LOOBY: -- OR OTHER REPRESENTATIVES OF THE
10:11AM 15 COMPANY.

10:11AM 16 AND SOME OF THEM ARE QUOTING PUBLIC APPEARANCES OF
10:11AM 17 MS. HOLMES, WHICH ARE ALSO ON THE GOVERNMENT'S EXHIBIT LIST IN
10:11AM 18 MANY CASES AS VIDEOS THAT THEY MAY PURPORT TO PLAY.

10:11AM 19 SO I DON'T THINK THAT THE ARTICLES THEMSELVES HAVE ANY
10:11AM 20 EVIDENTIARY VALUE SEPARATE AND APART FROM THOSE OTHER
10:12AM 21 STATEMENTS.

10:12AM 22 SO I DON'T SEE ANY ADMISSIONS IN THESE THAT HAVE LIKE AN
10:12AM 23 INDEPENDENT BASIS OR FOR ADMISSION.

10:12AM 24 THE COURT: AND I THINK YOU UNDERSTAND WHY I ASKED
10:12AM 25 THE QUESTION. THERE ARE QUOTES YOUR CLIENT APPEARED AT

10:12AM 1 CONFERENCES I THINK IN SOME OF THESE AND WAS INTERVIEWED, AND
10:12AM 2 THE ARTICLES SAYS MS. HOLMES WAS ASKED X AND SHE SAID X.

10:12AM 3 MR. LOOBY: RIGHT. AND SO THE ARTICLE AT THAT POINT
10:12AM 4 HAS A THRESHOLD HEARSAY ISSUE OF THE OUT-OF-COURT STATEMENT OF
10:12AM 5 THE REPORTER SAYING SHE SAID X.

10:12AM 6 THE COURT: CORRECT.

10:12AM 7 MR. LOOBY: AND IN SOME CASES IT'S PURPORTING TO
10:12AM 8 QUOTE AND OTHER TIMES IT IS PURPORTING TO PARAPHRASE AND THOSE
10:12AM 9 ARE EVEN MORE PROBLEMATIC IN SOME INSTANCES.

10:12AM 10 THE COURT: I THINK WE CAN PUT THOSE ASIDE, THE
10:12AM 11 PARAPHRASE, RIGHT.

10:12AM 12 MR. LOOBY: RIGHT, RIGHT. BUT EVEN THE QUOTATIONS,
10:12AM 13 THE SELECTION OF THEM THAT ARE PLACED IN THE ARTICLE WHERE I
10:12AM 14 WOULD SAY THAT THE HEARSAY ISSUE STILL HASN'T BEEN SURMOUNTED
10:12AM 15 BY THE GOVERNMENT.

10:12AM 16 SO I DON'T THINK THAT THE ARTICLES ARE ADMISSIBLE JUST BY
10:12AM 17 BASIS OF HAVING THE QUOTATIONS BECAUSE OF THAT HEARSAY ISSUE.

10:13AM 18 THE COURT: OR ANY PIECE OF THE ARTICLE THAT WOULD
10:13AM 19 IDENTIFY A QUOTE. NOT THE ARTICLE IN TOTO BUT JUST THE QUOTE.
10:13AM 20 THAT'S NOT PARSABLE IN YOUR VIEW?

10:13AM 21 MR. LOOBY: NO, YOUR HONOR, BECAUSE OF THAT HEARSAY
10:13AM 22 ISSUE OF THIS IS A REPORTER OR A NEWS AGENCY REPRODUCING AN
10:13AM 23 OUT-OF-COURT STATEMENT. SO THERE'S THE DOUBLE LAYER THERE.

10:13AM 24 SO -- YES.

10:13AM 25 THE COURT: ALL RIGHT.

10:13AM 1 MS. VOLKAR?

10:13AM 2 MS. VOLKAR: GOOD MORNING, YOUR HONOR.

10:13AM 3 THE COURT: I'M SORRY, MS. VOLKAR. WE'LL ADJUST
10:13AM 4 THESE SCREENS OR THE LECTERNS AT SOME TIME SO WE DON'T HAVE
10:14AM 5 THAT IS BAR IN FRONT OF YOURS.

10:14AM 6 DON'T DO IT NOW. THAT'S OKAY.

10:14AM 7 MS. VOLKAR: THANK YOU, YOUR HONOR. I'LL ALSO BE
10:14AM 8 BRIEF.

10:14AM 9 OF COURSE WE'RE HERE TODAY IN PART BECAUSE UNDER THE GUISE
10:14AM 10 OF FOLLOWING UP ON THE COURT'S PURPORTED INVITATION TO FILE
10:14AM 11 MORE MOTIONS, THE DEFENDANT IS IN FACT SEEKING TO SUBVERT
10:14AM 12 SEVERAL OF THE COURT'S THOUGHTFUL AND DETAILED RULINGS ON THE
10:14AM 13 MOTION IN LIMINE IN ITS MOTION IN LIMINE ORDER.

10:14AM 14 THE COURT HAS ALREADY ADDRESSED SEVERAL OF THESE MOTIONS
10:14AM 15 INCLUDING THE NEWS ARTICLE ONE. THE DEFENDANT COULD HAVE AT
10:14AM 16 THAT TIME ATTACHED MORE MOTIONS. THEY CERTAINLY SOUGHT BROAD
10:14AM 17 EXCLUSION AND DID NOT NECESSARILY HOLD BACK. THEY DID NOT
10:14AM 18 IDENTIFY THE SEVEN ARTICLES AT THAT TIME, AND SO I BELIEVE THE
10:14AM 19 COURT'S ORDER DENYING ESSENTIALLY THE NON-ADDRESSED ONES STILL
10:14AM 20 STANDS, ESPECIALLY GIVEN THAT NO TESTIMONY HAS YET COME IN.

10:14AM 21 SO THE GOVERNMENT'S FIRST POINT IS THAT THIS ARTICLE IS
10:14AM 22 PREMATURE. AT THIS POINT IN TIME NOTHING HAS ACTUALLY CHANGED
10:15AM 23 FROM THE COURT'S MOTION IN LIMINE ORDER. NO TESTIMONY HAS BEEN
10:15AM 24 GIVEN. THE TRIAL IS STILL IN THE FUTURE. AND SEEKING TO
10:15AM 25 EXCLUDE THESE SEVEN ARTICLES AT THIS POINT IN TIME DOES NOT

10:15AM 1 ALLOW FOR THE OTHER MANNER IN WHICH THE TESTIMONY MAY COME IN
10:15AM 2 IF WE WERE TO DISCUSS THIS EVEN A MONTH FROM NOW.

10:15AM 3 NOW, WHAT MIGHT THOSE METHODS BE?

10:15AM 4 WELL, FIRST, BY THE TIME THAT CERTAIN WITNESSES ARE
10:15AM 5 ALLOWED TO TESTIFY, THE TRUTH OF THE ARTICLE OR THE TRUTH OF
10:15AM 6 WHAT IS IN THE ARTICLE MAY ALREADY BE PROVEN AT TRIAL THROUGH
10:15AM 7 LIVE TESTIMONY, THROUGH WITNESSES WHO EXPERIENCED IT FIRSTHAND,
10:15AM 8 AND AT THAT POINT IN TIME THE GOVERNMENT MAY NOT SEEK TO
10:15AM 9 INTRODUCE THE ARTICLE FOR THE PURPOSES OF THE TRUTH BUT MERELY
10:15AM 10 FOR THE EFFECT ON THE LISTENER.

10:15AM 11 IN PARTICULAR, IF THESE ARTICLES WERE SHARED WITH BOARD
10:15AM 12 MEMBERS OR INVESTORS AS A WAY -- AN THE EFFECT ON THE READER TO
10:15AM 13 SAY, YES, THERE WAS AN ARTICLE THAT MADE CLAIMS, BUT HERE'S WHY
10:15AM 14 THE COMPANY DOESN'T BELIEVE THAT THAT ARTICLE WAS ACCURATE.

10:15AM 15 THE COURT: CAN I ASK YOU TO EXPAND ON THAT?

10:16AM 16 I NOTICED IN YOUR PLEADINGS YOU SUGGEST THE EFFECT ON THE
10:16AM 17 LISTENER, THE EFFECT ON THE READER. IF YOU COULD EXPAND ON
10:16AM 18 THAT SO I COULD CAPTURE EXACTLY WHAT YOU MEAN, WHO IS THE
10:16AM 19 READER AND WHO IS THE LISTENER IN THAT ANALYSIS?

10:16AM 20 MS. VOLKAR: ABSOLUTELY, YOUR HONOR.

10:16AM 21 THERE ARE SEVERAL WITNESSES, ONE OF WHOM THE DEFENDANT
10:16AM 22 HIRED IN PART TO HELP WITH THE MEDIA THAT CAME FROM
10:16AM 23 "THE WALL STREET JOURNAL'S" EXPOSE, SO TO SPEAK, OF WHAT WAS --
10:16AM 24 I'M HESITATING TO SAY THE TRUTH OF WHAT WAS GOING ON AT
10:16AM 25 THERANOS. I KNOW THAT'S, OF COURSE, WHAT IS IN DEBATE, BUT

10:16AM 1 "THE WALL STREET JOURNAL'S" OCTOBER 2015 ARTICLE CAUSED A
10:16AM 2 REACTION AND DEFENDANT HOLMES ACTUALLY HIRED PEOPLE TO HELP
10:16AM 3 RESPOND TO THAT MEDIA.

10:16AM 4 SO THERE ARE CERTAIN WITNESSES WHOSE JOB IT WAS TO FIELD
10:16AM 5 REPORTERS TO TALK TO THEM TO PROVIDE QUOTES OF MS. HOLMES TO
10:16AM 6 REBUT OR RESPOND IN THE MEDIA TO THESE CLAIMS.

10:16AM 7 AND THOSE ARTICLES WERE POINTED TO IN A MANNER OF SAYING
10:17AM 8 THE COMPANY IS HANDLING THIS, THE COMPANY IS RESPONDING TO
10:17AM 9 THIS, AND THEY WERE MEANT TO SHOW -- IN THE GOVERNMENT'S
10:17AM 10 PERSPECTIVE, THEY WERE A WAY OF CONTINUING THE FRAUD, THEY WERE
10:17AM 11 A WAY OF CONTINUING TO CONCEAL WHAT WAS GOING ON, THE TRUTH OF
10:17AM 12 WHAT WAS HAPPENING AT THERANOS.

10:17AM 13 SO OUR POINT WOULD BE JUST AT THIS MOMENT IN TIME THE
10:17AM 14 GOVERNMENT DOES NOT NECESSARILY PLAN TO MENTION THESE SPECIFIC
10:17AM 15 ARTICLES IN ITS OPENING, BUT AT THE SAME TIME IT'S HARD TO
10:17AM 16 PREDICT IF THEY WON'T BECOME RELEVANT LATER ON FOR BOARD
10:17AM 17 MEMBERS OR INVESTORS OR POTENTIAL WITNESSES TO SAY WHY THEY
10:17AM 18 DIDN'T NECESSARILY -- "THE WALL STREET JOURNAL" WASN'T SORT OF
10:17AM 19 THE COLLAPSE OF EVERYTHING AND BOARD MEMBERS DIDN'T NECESSARILY
10:17AM 20 PLEA IMMEDIATELY THEREAFTER.

10:17AM 21 THE COURT: I SEE. SO ITS EFFECT ON THAT GROUP OF
10:17AM 22 INDIVIDUALS THAT YOU'VE JUST MENTIONED, BOARD MEMBERS,
10:17AM 23 POTENTIAL INVESTORS, THAT'S THE EFFECT THAT YOU'RE SPEAKING OF?

10:17AM 24 MS. VOLKAR: AND, AGAIN, THAT'S ONE CATEGORY AND ONE
10:17AM 25 WAY TO GET AROUND THE HEARSAY.

1 ANOTHER WAY IS THE MEDIA PEOPLE THAT WERE HIRED IN ORDER
2 TO RESPOND TO "THE WALL STREET JOURNAL" ARTICLE THAT CAME OUT
3 AND TO ESSENTIALLY GO ON THE OFFENSIVE TO CLEAR THERANOS'S NAME
4 OF SORTS, THEY CAN ALSO TALK ABOUT -- SOMETIMES THEY WERE THE
5 ONES WHO WERE PROVIDING THE STATEMENTS TO THE MEDIA FOLKS, AND,
6 THEREFORE, THEY'RE OFTEN THE ONES PROVIDING THE QUOTES AND CAN
7 TALK ABOUT THE ACCURACY OF THOSE QUOTES.

8 THE COURT: THANK YOU.

9 I THINK YOU MENTIONED IN YOUR OPPOSITION THAT THE MOTION
10 IS PREMATURE FROM YOUR POSITION IN THAT YOU SUGGEST THAT, AS
11 YOU JUST DID, THAT YOU INDICATE THAT YOU, THE GOVERNMENT, IS
12 NOT GOING TO RAISE ANY OF THESE SEVEN ARTICLES IN THEIR OPENING
13 STATEMENT; AND THAT RATHER THE COURT SHOULD RESERVE ITS RULING
14 ON THIS; AND THAT YOU, THE GOVERNMENT, WILL ADVISE MS. HOLMES
15 AND THE COURT SHOULD YOU WISH TO INTRODUCE ANY OF THESE
16 ARTICLES OR ANY INFORMATION CONTAINED IN THE ARTICLE PRIOR TO
17 ITS ADMISSION OR PRIOR TO YOUR GOING FORWARD SUCH THAT THE
18 PARTIES WOULD HAVE AN OPPORTUNITY TO THEN DISCUSS THE
19 ADMISSIBILITY OF THE ARTICLE OR THE PORTION OR THE SPEAKER AND
20 THE REASONS FOR?

21 MS. VOLKAR: THAT'S CORRECT, YOUR HONOR.

22 THE COURT: MR. LOOBY, WHAT'S WRONG WITH THAT?

23 MR. LOOBY: WELL, I THINK, YOUR HONOR, I THINK THAT
24 THE GOVERNMENT'S EXHIBIT LIST IS NOW NUMBERING IN THE THOUSANDS
25 OF EXHIBITS AND TRIAL IS, YOU KNOW, MERE WEEKS AWAY AT THIS

10:19AM 1 POINT.

10:19AM 2 JUST FROM A TRIAL PREPARATION STANDPOINT, WE SUBMIT THAT
10:19AM 3 THE HEARSAY ISSUES IN THESE ARTICLES HAVE NOT BEEN SOLVED
10:19AM 4 EITHER BY THE OPPOSITIONS IN -- THE ARGUMENTS IN THE
10:19AM 5 GOVERNMENT'S OPPOSITION BRIEF OR IN THE NEW ARGUMENTS MADE HERE
10:19AM 6 TODAY. SO WE SUBMIT THAT THE -- IT'S RIPE FOR ADJUDICATION
10:19AM 7 NOW.

10:19AM 8 THE COURT: WELL, WHAT IS THE PREJUDICE OF WAITING
10:19AM 9 TO SEE IF THEY EVEN WISH TO USE THEM?

10:19AM 10 I TAKE THE MOTIONS, AND THIS MIGHT APPLY TO SOME OF THE
10:20AM 11 OTHER MOTIONS HERE AND NOT IN A PEJORATIVE SENSE, BUT THIS IS
10:20AM 12 -- FIRST OF ALL, LET ME JUST SAY AT A HIGH LEVEL, I THINK YOUR
10:20AM 13 TEAM HAS ACCEPTED THE COURT'S INVITATION THAT IT MENTIONED IN
10:20AM 14 DOCKET 798, ITS MIL ORDERS INDICATING AS TO SEVERAL, IF THE
10:20AM 15 PARTIES WISH TO RAISE SOMETHING IN THE FUTURE WITH MORE
10:20AM 16 SPECIFICITY, PARTICULARLY MS. HOLMES, THE COURT WOULD RECEIVE
10:20AM 17 THAT.

10:20AM 18 AND I TAKE YOUR FOUR MOTIONS THIS MORNING AS ACCEPTING
10:20AM 19 THAT INVITATION AND RAISING THOSE ISSUES, AND I APPRECIATE
10:20AM 20 THAT. AND THE OFFER WAS MADE, AND THAT'S WHAT WE'RE HAVING
10:20AM 21 THIS DISCUSSION ABOUT.

10:20AM 22 BUT ATTENDANT TO THAT I'M HAVE JUST CURIOUS IF, AS
10:20AM 23 MS. VOLKAR SAYS, WE'RE ON NOTICE NOW AND SHOULD WE WISH TO
10:20AM 24 INTRODUCE ANY OF THESE, WE'LL -- WE CERTAINLY KNOW WHAT THE
10:20AM 25 CURRENT OBJECTIONS ARE. THERE MAY BE ADDITIONAL OBJECTIONS

10:21AM 1 DEPENDING ON THE STATE OF THE EVIDENCE AT THE TIME THAT THESE
10:21AM 2 ARE SOUGHT TO BE INTRODUCED, AND THAT, THAT PLANE COULD CHANGE
10:21AM 3 BECAUSE WE DON'T KNOW WHAT WITNESSES MIGHT FOUNDATIONALLY BE
10:21AM 4 CALLED UPON TO TALK ABOUT SOME OF THESE ISSUES OR OTHERS THAT
10:21AM 5 MIGHT CHANGE THE LANDSCAPE OF ADMISSIBILITY.

10:21AM 6 MR. LOOBY: RIGHT.

10:21AM 7 THE COURT: I THINK THAT'S WHAT I HEAR MS. VOLKAR
10:21AM 8 SUGGESTING.

10:21AM 9 MR. LOOBY: YEAH. AND I THINK I DISAGREE WITH THAT
10:21AM 10 ANALYSIS FROM THE GOVERNMENT BECAUSE WHETHER OR NOT THERE IS
10:21AM 11 WITNESS TESTIMONY IN THE CASE THAT EITHER ECHOES OR PARALLELS
10:21AM 12 SOME OF THE KIND OF CONTENTIONS IN THE ARTICLES I DON'T THINK
10:21AM 13 WOULD BEAR ON THE HEARSAY ISSUES IN THE ARTICLES THEMSELVES IF
10:21AM 14 THEY'RE BEING OFFERED FOR THAT PURPOSE.

10:21AM 15 I DON'T THINK YOU CAN LIKE PROVE MID TRIAL THAT SOME
10:21AM 16 CONTENTION WAS TRUE OR NOT, AND THEN THE ARTICLE IS NO LONGER
10:21AM 17 HEARSAY BECAUSE SOME OTHER WITNESS IS VOUCHING FOR SOME FACT
10:21AM 18 CONTAINED WITHIN IT. I DON'T THINK THAT'S HOW IT WORKS.

10:21AM 19 BUT BEYOND THAT, WHAT I HEARD IS THAT THE EFFECT ON THE
10:21AM 20 READER. I CONCEIVE OF THAT AS THE SAME ARGUMENT, THE SAME
10:22AM 21 CONTEXT FOR THE COMPANY'S RESPONSE AND MS. HOLMES'S RESPONSE
10:22AM 22 THAT THE COURT ALREADY ADDRESSED IN ITS IN LIMINE RULING.

10:22AM 23 I UNDERSTAND WE'RE HERE ON THE EVE OF TRIAL, BUT WE HAD
10:22AM 24 HOPED THAT THIS PARTICULAR MOTION IN PARTICULAR WOULD BE RATHER
10:22AM 25 STRAIGHTFORWARD. THIS IS A CLEAN-UP MOTION. THESE ARTICLES

10:22AM 1 WITH DID NOT ATTACH TO THE PRIOR MOTION JUST TO LIMIT THE
10:22AM 2 NUMBER OF PAPERS.

10:22AM 3 SO I DON'T WANT TO BELABOR THE POINT, BUT I THINK THE
10:22AM 4 COURT'S ANALYSIS IS KIND OF THE RULE THAT WE'RE OPERATING UNDER
10:22AM 5 RIGHT NOW, AND THESE ARTICLES ARE EXCLUDED UNDER IT OR SHOULD
10:22AM 6 BE.

10:22AM 7 THE COURT: UNTIL AND UNLESS THERE'S OTHERWISE
10:22AM 8 EVIDENCE THAT SUGGESTS THEIR ADMISSIBILITY.

10:22AM 9 MR. LOOBY: CORRECT, AS THE NATURE OF ANY IN LIMINE
10:22AM 10 RULING FOR SURE, YOUR HONOR.

10:22AM 11 BUT I THINK AS OF RIGHT NOW IN TERMS OF WHETHER THIS
10:22AM 12 IN LIMINE RULING IS MORE OR LESS SUSCEPTIBLE TO RESOLUTION NOW
10:22AM 13 THAN ANY OTHER, I SUBMIT THAT IT IS.

10:22AM 14 THE COURT: OKAY. WELL, THANK YOU.

10:22AM 15 MS. VOLKAR, WHAT I THINK I HEAR YOU SAYING IS THANK YOU
10:23AM 16 FOR THE NOTICE AND WE'RE NOT GOING TO -- WE UNDERSTAND THE
10:23AM 17 COURT'S ORDER IN 798, AND WE'RE NOT GOING TO AT THIS TIME
10:23AM 18 INTRODUCE ANY OF THESE. IF WE INTEND TO, WE'LL CERTAINLY
10:23AM 19 INFORM THE COURT OF THAT. MS. HOLMES HAS THE RIGHT AT THAT
10:23AM 20 POINT TO LODGE ANY OBJECTIONS.

10:23AM 21 MS. VOLKAR: THAT'S RIGHT, YOUR HONOR. WE JUST
10:23AM 22 THINK IT'S SIMPLY PREMATURE AT THIS POINT IN TIME. I THINK
10:23AM 23 WE'RE IN NO DIFFERENT POSITION THAN WE WERE WHEN WE WERE
10:23AM 24 ARGUING THESE MOTIONS BEFORE YOUR HONOR MONTHS AGO AND NOT A
10:23AM 25 SINGLE WITNESS HAS TESTIFIED YET, AND, THEREFORE, I THINK IT'S

10:23AM 1 PREMATURE TO RULE ON THESE NOW.

10:23AM 2 THE COURT: ALL RIGHT. ANYTHING FURTHER, MR. LOOBY?

10:23AM 3 MR. LOOBY: NO, YOUR HONOR.

10:23AM 4 THE COURT: ALL RIGHT. THANK YOU VERY MUCH. I

10:23AM 5 APPRECIATE IT. THANK YOU.

10:23AM 6 LET'S TURN TO 899. THIS IS MS. HOLMES'S RENEWED MOTION TO

10:23AM 7 EXCLUDE CERTAIN DOCTOR TESTIMONY.

10:23AM 8 GOOD MORNING, MS. TREFZ.

10:23AM 9 MS. TREFZ: GOOD MORNING, YOUR HONOR.

10:23AM 10 THE COURT: WHAT WOULD YOU LIKE ME TO KNOW ABOUT

10:24AM 11 THIS?

10:24AM 12 MS. TREFZ: YOUR HONOR, THIS MOTION IS ALSO A

10:24AM 13 CLEAN-UP MOTION, AND AS THE COURT NOTED, THIS IS MS. HOLMES'S

10:24AM 14 RENEWED MOTION TO EXCLUDE CERTAIN DOCTOR TESTIMONY. WE VIEW IT

10:24AM 15 AS FAIRLY SIMPLE.

10:24AM 16 THE COURT'S MOTION IN LIMINE ORDER INDICATED THAT IF THE

10:24AM 17 GOVERNMENT HAD NOT PROVIDED UPDATED DISCLOSURES AS TO CERTAIN

10:24AM 18 OF THE DOCTOR EXPERT WITNESS POTENTIAL AREAS OF TESTIMONY THAT

10:24AM 19 WE COULD RENEW OUR MOTION.

10:24AM 20 WE AGREED WITH THE GOVERNMENT THAT THEY WOULD PROVIDE

10:24AM 21 AMENDED DISCLOSURES AS OF JULY 30TH. THEY DID THAT.

10:24AM 22 THEIR AMENDED DISCLOSURES SUBSTANTIALLY NARROWED THE

10:24AM 23 POTENTIAL SCOPE OF THE TESTIMONY AND IN PARTICULAR, YOU KNOW,

10:24AM 24 IDENTIFIED PARTICULAR PATIENTS, CUT OUT SOME OF THE DOCTORS.

10:24AM 25 ALL WE'RE ASKING FOR HERE IS A RULING THAT DOCTOR EXPERT

10:24AM 1 TESTIMONY ABOUT ALLEGEDLY INACCURATE TESTS BEYOND WHAT HAS BEEN
10:25AM 2 NOTICED IN THIS JULY 30TH LETTER BE EXCLUDED AS INSUFFICIENTLY
10:25AM 3 DISCLOSED UNDER RULE 16.

10:25AM 4 THE COURT: OKAY. THANK YOU.

10:25AM 5 I TAKE THIS -- I LOOKED AT THIS AND IT SAID, "JUDGE, WE
10:25AM 6 RECEIVED YOUR ORDER AND ON AUGUST 20TH WE WOULD LIKE TO DISCUSS
10:25AM 7 TO REMIND YOU AND HAVE THE GOVERNMENT SAY WHAT YOU SAID AND NO
10:25AM 8 MORE."

10:25AM 9 IS THIS JUST A REAFFIRMING OF THE COURT'S PREVIOUS ORDER?

10:25AM 10 MS. TREFZ: WELL, I THINK IT'S A LITTLE BIT
10:25AM 11 DIFFERENT.

10:25AM 12 IN A SENSE YES, BUT IN A SENSE IT'S A SLIGHTLY DIFFERENT
10:25AM 13 CONTEXT BECAUSE THE COURT TECHNICALLY DENIED OUR MOTION ON
10:25AM 14 RULE 16 BEFORE AND INVITED US TO RENEW THE MOTION. SO WE ARE
10:25AM 15 NOW RENEWING THE MOTION.

10:25AM 16 SO LIKE I SAID, IT'S A LITTLE BIT OF A CLEANUP. WE
10:25AM 17 UNDERSTAND THAT THE GOVERNMENT SAYS IT'S GOING TO HOLD ITSELF
10:25AM 18 TO THESE DISCLOSURES, WHICH IS GREAT. WE WOULD JUST APPRECIATE
10:25AM 19 AN ORDER MAKING THAT CLEAR, AND WE THINK THAT THAT'S
10:25AM 20 APPROPRIATE BECAUSE, YOU KNOW, THERE ARE STILL EXHIBITS ON
10:26AM 21 THEIR EXHIBIT LIST AND WITNESSES DISCLOSED THAT HAVE BEEN SORT
10:26AM 22 OF WE THINK DISCLAIMED BY THE UPDATED DISCLOSURE.

10:26AM 23 THE COURT: RIGHT. THEY'RE NOT ON THE LIST ANYMORE.

10:26AM 24 MS. TREFZ: WELL, THEY ARE IS THE PROBLEM. AND SO
10:26AM 25 WE JUST WANT TO MAKE CLEAR THAT THEY'RE NOT IF THAT MAKES

10:26AM 1 SENSE.

10:26AM 2 THE COURT: FOR THIS PURPOSE?

10:26AM 3 MS. TREFZ: WELL, FOR THIS PURPOSE BUT AT LEAST ONE
10:26AM 4 OF THE DOCTORS, FOR EXAMPLE, DR. ACHARYA, YOU KNOW, HIS CV IS
10:26AM 5 STILL ON THE GOVERNMENT'S EXHIBIT LIST AS OF MONDAY, AND HE WAS
10:26AM 6 STILL INCLUDED AS A POTENTIAL WITNESS ON THE GOVERNMENT'S -- ON
10:26AM 7 THE JUROR QUESTIONNAIRE. AND FROM OUR PERSPECTIVE WE'RE NOT
10:26AM 8 SURE WHAT OF HIS TESTIMONY, POTENTIAL TESTIMONY THAT HAS NOT
10:26AM 9 BEEN, THAT HAS NOT BEEN DISCLAIMED COULD EVEN POSSIBLY COME IN.

10:26AM 10 SO WE'RE JUST A LITTLE BIT WEARY, AND WE WOULD JUST LIKE
10:26AM 11 IT TO BE CLEAR.

10:26AM 12 THE COURT: OKAY. MS. VOLKAR, YOU'RE RISING TO
10:27AM 13 THIS?

10:27AM 14 MS. VOLKAR: I AM, YOUR HONOR. THANK YOU.

10:27AM 15 THE FIRST THING THAT STRIKES ME, YOUR HONOR, IS THAT
10:27AM 16 COUNSEL'S STATEMENT CONFIRMS THAT THIS IS SIMPLY A MOTION TO
10:27AM 17 RECONSIDER YOUR HONOR'S PRIOR RULING, AND THE GOVERNMENT
10:27AM 18 SUBMITS THAT IT IS ENTIRELY UNNECESSARY.

10:27AM 19 THE -- COUNSEL READS YOUR RULING CORRECTLY, BUT TAKES IT
10:27AM 20 AS AN INVITATION THAT THE GOVERNMENT DOES NOT SEE.

10:27AM 21 YOUR HONOR SAID, "IF THE GOVERNMENT DOES NOT PROVIDE
10:27AM 22 UPDATED DISCLOSURES, YOU COULD BRING A MOTION."

10:27AM 23 THEY ASKED FOR THOSE UPDATED DISCLOSURES BY JULY 30TH, AND
10:27AM 24 WE GAVE THEM. WE SUPPLEMENTED OUR DISCLOSURES, AND WE DID
10:27AM 25 EVERYTHING THAT THEY ASKED AND THIS COURT ORDERED US TO DO.

1 AT THIS POINT IN TIME A FURTHER ORDER IS ABSOLUTELY
2 UNNECESSARY.

3 AND THE GOVERNMENT'S CONCERN HERE IS REALLY BASED ON
4 SEVERAL OF THE DISPUTES THAT WE'VE HAD WITH THE DEFENSE AND
5 WHAT THIS ORDER MIGHT MEAN.

6 WHAT DO WE MEAN BY THAT? AS WE DESCRIBED IN OUR
7 OPPOSITION, THIS IS AN EXAMPLE THE DEFENSE MIGHT TAKE THE
8 SUPPLEMENTAL DISCLOSURE TO BE THE EQUIVALENT OF AN EXPERT
9 REPORT AND TRY TO CLAIM THAT THE WITNESSES CANNOT TESTIFY
10 BEYOND WHAT THE GOVERNMENT HAS DISCLOSED IN A NOTICE DISCLOSURE
11 AS THE GENERAL TOPICS OF WHAT THEY MIGHT TALK ABOUT.

12 THEY MIGHT ALSO USE THIS TO PROHIBIT ADDITIONAL EXPERT
13 TESTIMONY OR OTHER WAYS THAT WE HAVEN'T YET THOUGHT ABOUT.

14 BUT AT THE POINT IN TIME WHAT WE'RE TRYING TO SAY IS NO
15 FURTHER ORDER IS NEEDED ON THIS TOPIC. THE COURT'S MOTION IN
16 LIMINE ORDER ABSOLUTELY ADDRESSED THIS, TOLD THE GOVERNMENT
17 WHAT TO DO, THE GOVERNMENT FOLLOWED EXACTLY WHAT THE COURT SAID
18 TO DO AND PROVIDED ITS SUPPLEMENTAL DISCLOSURES.

19 NOW, TO THE EXTENT THAT COUNSEL TALKS ABOUT THE ADDITIONAL
20 DOCUMENT OR THE JUROR QUESTIONNAIRE, OF COURSE WE JUST DECIDED
21 ON MONDAY THAT THE GOVERNMENT WILL BE PROVIDING THE FIRST HALF
22 OF ITS WITNESSES BY A CERTAIN DATE, THE SECOND HALF OF ITS
23 WITNESSES.

24 DEFENSE COUNSEL IS GOING TO HAVE ALL OF THE NOTICE THAT IT
25 NEEDS IN ORDER TO PREPARE ITS DEFENSE AS WE GO FORWARD.

10:28AM 1 OF COURSE THE GOVERNMENT WAS REFINING ITS CASE AS TIME
10:29AM 2 WENT ALONG, BUT THAT DOES NOT MEAN THAT WE'RE GOING TO GO
10:29AM 3 BEYOND OR AGAINST OUR SUPPLEMENTAL DISCLOSURES.

10:29AM 4 WE MADE THEM ACCORDING TO THE COURT'S ORDER, AND WE STAND
10:29AM 5 BY THEM. NO FURTHER ORDER IS NEEDED TO HOLD THE GOVERNMENT TO
10:29AM 6 ITS DISCLOSURES.

10:29AM 7 THE COURT: DOES THE GOVERNMENT UNDERSTAND ITS
10:29AM 8 OBLIGATIONS, RESTRICTIONS, AND LIMITATIONS BASED ON THE COURT'S
10:29AM 9 ORDER IN DOCUMENT 798?

10:29AM 10 MS. VOLKAR: IT DOES, YOUR HONOR.

10:29AM 11 THE COURT: DO YOU NEED ANY CLARITY ABOUT THAT?

10:29AM 12 MS. VOLKAR: NO, WE DO NOT, YOUR HONOR.

10:29AM 13 THE COURT: THANK YOU.

10:29AM 14 MS. TREFZ.

10:29AM 15 MS. TREFZ: THE ONLY THING I WOULD SAY, YOUR HONOR,
10:29AM 16 IS THAT I'M A LITTLE CONFUSED BY THE OBJECTION IN PART BECAUSE
10:29AM 17 WHAT I HEARD MS. VOLKAR SAY WAS, YOU KNOW, WE'RE CONCERNED THAT
10:29AM 18 THEY THINK THAT IF THE WITNESS TESTIFIES OUTSIDE OF WHAT HAS
10:29AM 19 BEEN DISCLOSED THAT, YOU KNOW, WE'RE GOING TO GET AN OBJECTION.

10:29AM 20 I THINK TWO MINOR POINTS RELATED TO THAT. ONE IS THAT,
10:29AM 21 INDEED, IF THE WITNESS TESTIFIES OUTSIDE OF WHAT HAS BEEN
10:29AM 22 NOTICED IN THE EXPERT DISCLOSURE ON EXPERT TOPICS, YOU ARE
10:30AM 23 ABSOLUTELY GOING TO GET AN OBJECTION ON THAT, AND THAT IS TRUE
10:30AM 24 WHETHER OR NOT THE COURT ISSUES AN ORDER. IT IS ACTUALLY NOT
10:30AM 25 REALLY, I THINK, ADDRESSED BY THE REQUESTED ORDER.

10:30AM 1 OUR REQUESTED ORDER IS FAIRLY SPECIFIC, AND IT IS
10:30AM 2 ESSENTIALLY THESE ARE THE PATIENTS, AND THESE ARE THE TESTS
10:30AM 3 THAT THESE DOCTORS ARE GOING TO TALK ABOUT, AND THEY'RE NOT
10:30AM 4 GOING TO TALK ABOUT ANY OTHER PATIENTS, AND THEY'RE NOT GOING
10:30AM 5 TO TALK ABOUT ANY OTHER TESTS, AND THERE'S NOT GOING TO BE A
10:30AM 6 NEW DOCTOR TO COME IN TO TALK ABOUT AN ADDITIONAL PATIENT OR
10:30AM 7 TEST. THAT'S WHAT WE'RE WORRIED ABOUT HERE.

10:30AM 8 AND OBVIOUSLY THE GOVERNMENT HAS ITS OBLIGATION WITH
10:30AM 9 RESPECT TO THE REST OF THE DISCLOSURES. WE'VE MADE OUR
10:30AM 10 OBJECTIONS, YOU KNOW, IN THE PAST. WE HAD A VERY LONG
10:30AM 11 DISCUSSION ABOUT IT BEFORE. WE'RE NOT LOOKING TO RELITIGATE
10:30AM 12 THAT.

10:30AM 13 ALL WE'RE TRYING TO DO IS SAY THESE ARE THE TESTS, THESE
10:30AM 14 ARE THE PATIENTS, AND THAT'S IT.

10:30AM 15 THE COURT: I THINK THAT'S WHAT THE DISCLOSURE SAYS.

10:30AM 16 MS. VOLKAR: THAT'S CORRECT, YOUR HONOR.

10:30AM 17 THE COURT: RIGHT.

10:30AM 18 MS. VOLKAR: IN FACT, YOUR HONOR, IF I MAY?

10:31AM 19 COUNSEL'S STATEMENTS AGAIN SHOW EXACTLY WHAT THE
10:31AM 20 GOVERNMENT IS CONCERNED BY, WHICH IS THAT THE DISCLOSURE IS
10:31AM 21 GOING TO BE USED BEYOND WHAT IT IS, A DISCLOSURE MADE PURSUANT
10:31AM 22 TO THE RULES, PURSUANT TO THIS COURT'S ORDER, AND, OF COURSE,
10:31AM 23 THE GOVERNMENT IS GOING TO BE BOUND BY ITS DISCLOSURE.

10:31AM 24 WE ABSOLUTELY UNDERSTAND OUR OBLIGATIONS. BUT TO THE
10:31AM 25 EXTENT THAT ANY FURTHER ORDER OF THE COURT IS GOING TO BE USED

1 AS SOMETHING TO BE USED AGAINST THE GOVERNMENT AS A TOOL IN THE
2 FUTURE PROCEEDINGS, THAT IS ABSOLUTELY WHAT WE ARE CONCERNED
3 ABOUT AND WHY WE THINK THERE'S NO NEED FOR A FURTHER ORDER.

4 THE COURT: OKAY. GREAT. THANK YOU VERY MUCH.
5 THANKS FOR THE DISCUSSION. I APPRECIATE IT.

6 LET'S MOVE TO 897, AND THIS IS MS. HOLMES'S MOTION TO
7 PARTIALLY REDACT AGENCY REPORTS.

8 MR. LOOBY, GOOD MORNING AGAIN.

9 MR. LOOBY: GOOD MORNING AGAIN, YOUR HONOR.

10 SO AS WE NOTED IN OUR REPLY BRIEF, THE PARTIES AGREE THAT
11 THE THREE REPORTS ARE NOT FULLY ADMISSIBLE IN THEIR UNREDACTED
12 FORM. THE REMAINING DISPUTES ARE RELATED TO THE TIMING FOR
13 WHEN THE COURT SHOULD RULE ON THE THREE GROUPINGS OF
14 REDACTIONS.

15 AS FOR ALL BUT ARGUABLY ONE OF THOSE GROUPINGS THE
16 REDACTIONS FOR DOUBLE HEARSAY, WHICH I'LL ADDRESS LAST, WE
17 SUBMIT THAT THE COURT MAY RULE ON THE REDACTIONS NOW.

18 SO AS FOR THE REDACTIONS FOR TESTS NOT IN THE BILL OF
19 PARTICULARS, THE GOVERNMENT HAS ARTICULATED NO PERMISSIBLE
20 PURPOSE FOR OFFERING PORTIONS OF THE CMS REPORT THAT RELATE
21 EXCLUSIVELY TO THOSE TESTS.

22 TO BE HONEST, I WOULD BE HARD PRESSED TO THINK OF ONE FOR
23 THEM. THE GOVERNMENT OFFERED THE CMS FINDINGS AS EVIDENCE
24 BEARING ON ACCURACY AND RELIABILITY OF THERANOS'S TESTS.

25 THE COURT RULED ON THE WHOLE THAT THEY WERE RELEVANT FOR

10:33AM 1 THAT PURPOSE.

10:33AM 2 THE REDACTIONS SIMPLY SEEK TO SQUARE THAT RULING WITH THE
10:33AM 3 COURT'S SEPARATE RULING ON THE BILL OF PARTICULARS AND THE
10:33AM 4 TESTS NOT AT ISSUE IN THE CASE.

10:33AM 5 SO AS WE UNDERSTAND IT, THE GOVERNMENT HAS TWO MAIN
10:33AM 6 COMPLAINTS FOR THIS CATEGORY OF REDACTIONS. THE FIRST IS THAT
10:33AM 7 THEY WEREN'T GIVEN A CHANCE TO ARTICULATE ANY PURPOSE AND THE
10:33AM 8 SECOND RELATES TO THE EXTENT OF THE REDACTIONS NECESSARY FOR
10:33AM 9 THIS PURPOSE.

10:33AM 10 ON THE FIRST ARGUMENT WE RESPECTFULLY SUBMIT THAT THE
10:33AM 11 OPPOSITION BRIEF WAS JUST THAT OPPORTUNITY TO ARTICULATE A NEW
10:33AM 12 RELEVANCE THEORY FOR THESE PORTIONS OF THE REPORT AND THE
10:33AM 13 GOVERNMENT CHOSE TO FOREGO IT.

10:33AM 14 ON THE SECOND POINT, THE PORTION OF THE REPORT THAT DEALS
10:33AM 15 WITH TESTS THAT ARE NOT AT ISSUE IN THIS CASE IS WHAT IT IS,
10:33AM 16 AND THAT'S BECAUSE WE HAVE TO MEET THE CMS REPORT WHERE IT IS.

10:34AM 17 THE REALITY THAT LARGE PORTIONS OF THE REPORT ARE
10:34AM 18 IRRELEVANT, IT NECESSARILY FOLLOWS FROM THE FACT THAT THERANOS
10:34AM 19 OFFERED A MUCH BROADER MENU OF TESTS THAN THOSE THAT THE
10:34AM 20 GOVERNMENT HAS INCLUDED IN ITS INDICTMENT IN THIS CASE.

10:34AM 21 SO IT'S NOT SURPRISING THAT AN AUDIT OF THE OVERALL LAB
10:34AM 22 WOULD SWEEP IN A LOT OF FINDINGS THAT ARE IRRELEVANT.

10:34AM 23 AND THOSE FINDINGS HAVE NO PLACE IN THE CASE UNDER THE
10:34AM 24 COURT'S ORDER, AND WE SUBMIT THAT THE COURT SHOULD ADOPT OUR
10:34AM 25 PROPOSED REDACTIONS FOR THIS PURPOSE.

10:34AM 1 SO AS FOR THE REDACTIONS FOR HIGH LEVEL OBSERVER ANALYSIS
10:34AM 2 UNDER RULE 803(8) (A), WE SUBMIT THAT THE COURT HAS BEFORE IT
10:34AM 3 WHAT IT NEEDS TO RULE ON THESE REDACTIONS AS WELL. THESE ARE
10:34AM 4 LIMITED REDACTIONS TARGETED AT PORTIONS OF THE REPORT THAT
10:34AM 5 CONTAIN EVALUATIVE CONCLUSIONS THAT GO BEYOND FACTUAL
10:34AM 6 OBSERVATIONS.

10:34AM 7 SO IN TERMS OF THE VOLUME OF THE PROPOSED REDACTIONS,
10:34AM 8 THESE ARE ACTUALLY A MUCH SMALLER PORTION OF THE PROPOSED
10:35AM 9 REDACTIONS IN THE REPORTS.

10:35AM 10 THE PARTIES DISAGREE HERE --

10:35AM 11 THE COURT: I'M SORRY TO INTERRUPT HERE. ARE THESE
10:35AM 12 EXHIBIT 4?

10:35AM 13 MR. LOOBY: YES. SO THIS IS -- EXHIBIT 4 IS THE
10:35AM 14 FORM 483 FOR THE PALO ALTO FACILITY WITH OUR PROPOSED
10:35AM 15 REDACTIONS FOR THIS PURPOSE.

10:35AM 16 THE COURT: SO LET ME ASK YOU, MR. LOOBY -- AND
10:35AM 17 THANKS FOR PROVIDING YOUR SUGGESTED REDACTIONS. 898-4, PAGE 2
10:35AM 18 OF 8 IT -- UNDER OBSERVATION 1 I THINK YOU INDICATE WHAT YOUR
10:35AM 19 DESIRED REDACTIONS ARE. THOSE ARE THE SAME ON PAGE 4,
10:35AM 20 OBSERVATIONS 2, 3, 4.

10:35AM 21 MR. LOOBY: YES.

10:35AM 22 THE COURT: AS WELL AS OBSERVATION 5.

10:35AM 23 MR. LOOBY: YES.

10:35AM 24 THE COURT: AND IT'S THAT ONE SENTENCE, ISN'T IT,
10:35AM 25 "DESIGN VALIDATION DID NOT ENSURE THAT THE DEVICE CONFORMS TO

10:35AM 1 DEFINED USER NEEDS AND INTENDED USES"?

10:35AM 2 MR. LOOBY: YES, YOUR HONOR.

10:35AM 3 SO THIS PORTION OF THE OBSERVATION IS LIKE THE TOP LEVEL
10:36AM 4 EVALUATIVE CONCLUSION, AND IT'S TIED TO SOME REGULATORY
10:36AM 5 REQUIREMENT OR OBLIGATION, AND IT'S SUPPORTED AFTER THE --
10:36AM 6 SPECIFICALLY BY FACTUAL OBSERVATIONS OR ELABORATION, AND WE
10:36AM 7 PROPOSE TO REDACT THOSE UNDER THE COURT'S ANALYSIS.

10:36AM 8 WE UNDERSTAND THAT THE COURT -- UNDER THE COURT'S ANALYSIS
10:36AM 9 THAT LARGE PORTIONS OF THESE REPORTS ARE GOING -- WERE HELD TO
10:36AM 10 BE ADMISSIBLE UNDER SUBSECTION 2 OF THE RULE, BUT WE SUBMIT
10:36AM 11 THAT UNDER THE COURT'S ANALYSIS AND CONSISTENT WITH IT IN THE
10:36AM 12 ROSA CASE, WHICH IS CITED, THAT THIS IS THE TYPE OF REDACTION
10:36AM 13 THAT EVEN IN A REPORT THAT FALLS UNDER THAT RULE IS STILL
10:36AM 14 SUBJECT TO PARTIAL EXCLUSION.

10:36AM 15 THE GOVERNMENT SAID, OH, THESE ARE SO SIMPLE. WHY DID
10:36AM 16 THESE NEED TO BE REDACTED?

10:36AM 17 WE SUBMIT, YOUR HONOR, THEY HAVE IT ALL WRONG. THESE ARE
10:36AM 18 ACTUALLY PORTIONS OF THE REPORT THAT REFLECT LIKE A LATER IN
10:36AM 19 TIME EVALUATION OF THE RECORD TO A REGULATORY STANDARD. SO
10:37AM 20 THEY DO REFLECT A HIGH LEVEL ANALYSIS OF REGULATORY EXPERTISE
10:37AM 21 AND REGULATORY THINKING.

10:37AM 22 THE COURT: THANK YOU.

10:37AM 23 WHEN I LOOKED AT THE FORM, THIS IS THE FDA 483 FORM AND IN
10:37AM 24 THE SECOND BOX -- ACTUALLY, THE FIRST BOX BELOW THE
10:37AM 25 INFORMATION, THAT IS, THE DISTRICT ADDRESS AND THE NAME OF THE

10:37AM 1 INDIVIDUAL SERVED, IF YOU LOOK IN THAT BOX, IT DESCRIBES WHAT
10:37AM 2 THE DOCUMENT IS, AND I THINK IN THAT BOX IT USES THE WORD
10:37AM 3 "OBSERVATIONS" I THINK FIVE TIMES.

10:37AM 4 MR. LOOBY: YES.

10:37AM 5 THE COURT: AND IT TALKS ABOUT OBSERVATIONS.

10:37AM 6 AND THEN IN THE NEXT LARGE BOX THERE'S ANOTHER WORD
10:37AM 7 "OBSERVATIONS" USED AGAIN.

10:37AM 8 AND THEN IN THE LARGE BOX THAT IS ACTUALLY THE REPORTING
10:37AM 9 PART OF THE BOX IT STARTS OFF TALKING ABOUT "WE OBSERVED,
10:37AM 10 DURING THE INSPECTION WE OBSERVED."

10:37AM 11 AND THEN IT SAYS, AS THE GOVERNMENT FORMS TEND TO DO,
10:37AM 12 REPETITIVE, OBSERVATION 1. AND THEN IT HAS -- THE NEXT THING
10:38AM 13 IS THE SENTENCE THAT WE TALKED ABOUT THAT YOU WOULD LIKE
10:38AM 14 REDACTED.

10:38AM 15 MR. LOOBY: YES.

10:38AM 16 THE COURT: IT SEEMS TO BE, AT LEAST FROM THE
10:38AM 17 VERBIAGE, THAT THIS IS ALL OBSERVATIONAL AND NOT EVALUATIVE.

10:38AM 18 MR. LOOBY: SO, YOUR HONOR, I THINK IT'S -- THE
10:38AM 19 LINGO IN THE 483 IS OBSERVATION, THE ENTIRE KIND OF, YOU KNOW,
10:38AM 20 THE ENTIRE CITATION IS FRAMED AS THAT.

10:38AM 21 BUT IT ACTUALLY GOES BEYOND THAT. I THINK THERE'S THE
10:38AM 22 MONICKER OBSERVATION OF USING THAT WORD, AND THAT WORD ALIGNS
10:38AM 23 WITH THE ANALYSIS IN THE CASES AND THE RULE, BUT I THINK IT'S
10:38AM 24 ALMOST MORE OF A COINCIDENCE IN THAT SENSE BECAUSE THESE ARE --
10:38AM 25 TO BRING US OVER TO THE CMS REPORT, WHICH I THINK PRESENTS AN

1 ANALOGOUS SITUATION, THOSE ARE CALLED DEFICIENCIES, BUT THEY'RE
2 STRUCTURED ALMOST THE SAME WAY, WHICH IS, YOU KNOW, HERE'S THE
3 STANDARD THAT -- WE CAME AND WE LOOKED AT SOME EVIDENCE, HERE'S
4 THE EVIDENCE, AND THEN HERE'S OUR CONCLUSION.

5 SO THIS WHOLE THING IS FRAMED AS AN OBSERVATION, BUT WE
6 SUBMIT THAT THE SENTENCE THAT WE'VE PROPOSED TO BE REDACTED IS
7 ACTUALLY AN EVALUATIVE CONCLUSION WITHIN THAT OBSERVATION.

8 SO I UNDERSTAND, YOUR HONOR, THE WAY THAT THE FORM IS LAID
9 OUT. IT COULD BE SUSCEPTIBLE TO BEING READ AS THESE ARE ALL
10 JUST FACTS THAT WE SAW LIKE LYING AROUND WHEN WE WERE WALKING
11 THROUGH THE LABORATORY OR LOOKING AT THE DOCUMENTATION, BUT IF
12 YOU LOOK AT THE CONTENT OF THE SENTENCE, IT'S ACTUALLY A LITTLE
13 BIT MORE THAN THAT.

14 THE COURT: WELL, WHEN I COMPARE THAT ONE SENTENCE,
15 AND THEN BELOW IN EACH OF THE EXHIBITS THAT WE'VE TALKED ABOUT,
16 EACH OF THOSE THAT WE'VE TALKED ABOUT, IT SEEMS LIKE THE
17 LANGUAGE, FOR EXAMPLE, AFTER THE SENTENCE THAT WE WERE JUST
18 DISCUSSING IT, THEN THE NEXT WORD IS "SPECIFICALLY."

19 AND THEN IT LISTS A AND B. AND THEY'RE CORRECT, IT IS
20 VERY SPECIFIC, ISN'T IT? IT TALKS ABOUT FAILURE TO ADDRESS ALL
21 ASSAYS OF THE ASSAYS ADDRESSED, AND THEN IT LISTS THEM.
22 THERE'S NO REFERENCE TO ANY DOCUMENTATIONS TO ADDRESS FAILURES.
23 IT'S SPECIFIC INFORMATION.

24 AND IT SEEMS THAT THAT IS MORE, TO YOUR POINT, THAT SEEMS
25 TO BE MORE CLOSER TO YOUR POINT THAN THE ONE SENTENCE THAT YOU

10:40AM 1 SEEK TO HAVE REDACTED.

10:40AM 2 MR. LOOBY: I UNDERSTAND THAT.

10:40AM 3 I THINK THE WAY I READ IT IS THAT YOU PROVIDED THIS TEST
10:40AM 4 PLAN ASSAY, AND THEN THE TITLE OF THE REPORT, AND THEN THIS IS
10:40AM 5 THE -- COMING AFTER IT IS LIKE THIS IS WHAT WE OBSERVED IN THE
10:40AM 6 REPORT. WE LOOKED AT THE REPORT, AND THIS IS HOW WE INTERPRET
10:40AM 7 WHAT IT IS SAYING WHAT IS IN IT, WHAT IS NOT IN IT.

10:40AM 8 AND THEN YOU GO UP TO THE TOP AND THEY SAY, "BASED ON
10:40AM 9 THAT, BASED ON THAT, WE DON'T THINK THAT THIS DOCUMENTATION
10:40AM 10 ENSURES THE DEVICE CONFORMS TO DEFINE USER NEEDS AND INTENDED
10:40AM 11 USES." THAT'S AN FDA LIKE REGULATORY REQUIREMENT.

10:40AM 12 SO I THINK EVEN THOUGH THESE LATER FACTS ARE MORE
10:40AM 13 SPECIFIC, THEY'RE ACTUALLY CHARACTERIZING A DOCUMENT THAT THE
10:41AM 14 AGENCY DID REVIEW, AND I GUESS YOU COULD SAY OBSERVED.

10:41AM 15 AND THEN THE TOP LEVEL CONCLUSION THAT WE'VE PROPOSED TO
10:41AM 16 REDACT IS, OKAY, WHAT DOES THAT MEAN IN TERMS OF THE COMPANY'S
10:41AM 17 REGULATORY COMPLIANCE?

10:41AM 18 THE COURT: I SEE.

10:41AM 19 COULD A WITNESS CLEAR UP THAT, IF A WITNESS WERE PRODUCED
10:41AM 20 TO TESTIFY AS TO WHAT WAS DONE, WHAT THESE MEAN, WOULD THAT
10:41AM 21 REDUCE YOUR ANXIETY ABOUT REDACTION?

10:41AM 22 MR. LOOBY: WELL, I THINK, YOUR HONOR, THIS WOULD
10:41AM 23 STILL BE AN OUT-OF-COURT STATEMENT. SO EVEN IF A WITNESS COULD
10:41AM 24 COME IN, AND IT WAS ONE OF THE INSPECTORS OR SOMEONE WHO COULD
10:41AM 25 SPEAK FROM THEIR PERSONAL KNOWLEDGE ABOUT WHAT WAS FOUND IN THE

10:41AM 1 INSPECTION, I THINK THAT LIVE TESTIMONY WOULDN'T POSE -- IT MAY
10:41AM 2 POSE SOME OTHER ISSUES, BUT IT WOULDN'T POSE ANY HEARSAY ISSUES
10:41AM 3 AS A REPORT ADMITTED UNDER THE EXCEPTION FOR MATTERS OBSERVED
10:42AM 4 UNDER A DUTY TO REPORT.

10:42AM 5 SO I THINK THIS QUESTION ABOUT THE ADMISSIBILITY OF THE
10:42AM 6 REPORT IS SEPARATE FROM THAT. SO I'M NOT SURE IF THAT WOULD
10:42AM 7 AFFECT OUR POSITION.

10:42AM 8 THE COURT: OKAY. ALL RIGHT.

10:42AM 9 LET ME ASK YOU IF I MADE A COMMENT ON 898-6, AND THAT'S
10:42AM 10 PAGE 6.

10:42AM 11 MR. LOOBY: YES, YOUR HONOR.

10:42AM 12 THE COURT: YOU HAVE THREE SPECIFIC REASONS TO ASK
10:42AM 13 THAT THIS BE REDACTED AS WELL AS THE FOLLOWING PAGES, I
10:42AM 14 BELIEVE. WELL, IT'S JUST A, B, C AS TO THAT AND THE FOLLOWING
10:42AM 15 PAGE.

10:42AM 16 MR. LOOBY: YES. AND WE DID THE CODING JUST BECAUSE
10:42AM 17 IT IS SUCH A VOLUMINOUS REPORT.

10:42AM 18 SO WHEN AN ENTIRE TEST -- WHEN AN ENTIRE DEFICIENCY
10:42AM 19 RELATES TO A TEST NOT ISSUED, IT WILL SOMETIMES CAPTURE WITHIN
10:43AM 20 IT EVALUATIVE CONCLUSIONS THAT OTHERWISE WOULD BE REDACTABLE,
10:43AM 21 BUT BECAUSE THAT'S THE BLANKET REDACTION THAT KIND OF COVERS
10:43AM 22 IT. SO YOU'LL SEE OFTENTIMES THERE'S A, B, AND C APPLYING TO
10:43AM 23 ALL OF THEM.

10:43AM 24 THE COURT: OKAY. WELL, LET'S WAIT FOR FURTHER
10:43AM 25 DISCUSSION AFTER I HEAR FROM THE GOVERNMENT.

10:43AM 1 ANYTHING ELSE YOU WANT ME TO --

10:43AM 2 MR. LOOBY: YES. I DID JUST WANT TO TALK ABOUT THE
10:43AM 3 CMS COVER LETTER FOR A MOMENT.

10:43AM 4 THE COURT: RIGHT.

10:43AM 5 MR. LOOBY: SO WE DISAGREE WITH THE GOVERNMENT THAT
10:43AM 6 THE COURT'S MAY ORDER CAN AND SHOULD BE READ TO HAVE ALREADY
10:43AM 7 ADMITTED THE CMS COVER LETTER.

10:43AM 8 THE COURT: SO THAT'S AN INTERESTING ISSUE -- I KEEP
10:43AM 9 INTERRUPTING, AND I APOLOGIZE, MR. LOOBY, BUT I JUST WANT TO
10:43AM 10 CAPTURE MY THOUGHT.

10:43AM 11 MR. LOOBY: YES.

10:43AM 12 THE COURT: IT SEEMS WHEN WE WERE DISCUSSING THE
10:43AM 13 MOTIONS IN LIMINE, I BELIEVE THE GOVERNMENT WAS ACCURATE IN
10:43AM 14 SUGGESTING THAT YOUR TEAM TALKED ABOUT THE COVER LETTER AND
10:43AM 15 YOUR RESPONSE, AND IT WAS PART OF THE CONVERSATION REGARDING
10:43AM 16 THE CMS. YOU CALLED IT OUT.

10:44AM 17 AND, OF COURSE, THE COURT DID NOT PARSE OUT EACH PAGE OF
10:44AM 18 THE CMS REPORT THAT IT SAID IT WAS GOING TO ALLOW IN. IT SAID
10:44AM 19 THE CMS REPORT IS IN.

10:44AM 20 AND I THINK, MS. VOLKAR -- I DON'T MEAN TO SPEAK FOR
10:44AM 21 HER -- BUT IT SEEMS THAT THE GOVERNMENT'S POSITION IS, WELL, IT
10:44AM 22 WAS PART OF THE DISCUSSION AND IN FOR A PENNY, YOU KNOW, IT ALL
10:44AM 23 WAS SUBSUMED IN THAT.

10:44AM 24 AND YOU THINK DIFFERENTLY?

10:44AM 25 MR. LOOBY: I THINK DIFFERENTLY. AND, YOUR HONOR, I

10:44AM 1 REMEMBER IT WELL, OUR EXCHANGE ON THIS --

10:44AM 2 THE COURT: RIGHT.

10:44AM 3 MR. LOOBY: -- BECAUSE WE TALKED ABOUT THE IMMEDIATE
10:44AM 4 JEOPARDY FINDING AND WHETHER OR NOT THAT WAS RELEVANT OR
10:44AM 5 UNFAIRLY PREJUDICIAL.

10:44AM 6 AND THE IMMEDIATE JEOPARDY FINDING DOES APPEAR IN THE
10:44AM 7 LETTER, AND I THINK THE CONTEXT IS IMPORTANT THAT WE HAD MOVED
10:44AM 8 NOT TO EXCLUDE NOT JUST THE FORM 2567 AND ITS FINDINGS, BUT ALL
10:44AM 9 TESTIMONY AND EVIDENCE RELATING TO THE CMS INSPECTION AND ITS
10:44AM 10 FINDINGS.

10:44AM 11 AND WHEN WE WERE HAVING THAT EXCHANGE, I UNDERSTOOD IT TO
10:44AM 12 BE ABOUT, WELL, IS THIS RELEVANT? IS IT UNFAIRLY PREJUDICIAL?

10:44AM 13 AND I UNDERSTAND, YOUR HONOR -- WE UNDERSTAND YOUR HONOR'S
10:45AM 14 RULING ON THAT, BUT WE DON'T UNDERSTAND A RELEVANCE OR UNFAIR
10:45AM 15 PREJUDICE RULING MEANING THAT ANY OUT-OF-COURT STATEMENT ABOUT
10:45AM 16 THE IMMEDIATE JEOPARDY FINDING IN ANY DOCUMENT IS NOT HEARSAY
10:45AM 17 BECAUSE IT RELATES TO A MATTER OBSERVED.

10:45AM 18 WE SUBMIT THAT ANY OUT-OF-COURT STATEMENT WOULD STILL NEED
10:45AM 19 TO FIT WITHIN A HEARSAY EXCEPTION.

10:45AM 20 THE GOVERNMENT HAD MOVED TO ADMIT SPECIFICALLY THE REPORT
10:45AM 21 ITSELF BECAUSE THEIR REQUESTED RELIEF WAS MORE NARROW, AND THE
10:45AM 22 COURT'S HEARSAY ANALYSIS PRECEDED WITH RESPECT TO THE REPORT.

10:45AM 23 SO WE DON'T THINK THAT THE CMS LETTER FITS WITHIN THE
10:45AM 24 EXCEPTION THAT THE REPORT HAS BEEN RULED TO FALL UNDER FOR ALL
10:45AM 25 OF THE REASONS STATED IN OUR BRIEFING, WHICH THE GOVERNMENT

10:45AM 1 LARGELY IGNORES.

10:45AM 2 THE COURT: OKAY. THANK YOU.

10:45AM 3 I INTERRUPTED YOU, MR. LOOBY. DID YOU WANT TO --

10:45AM 4 MR. LOOBY: OH. JUST FINALLY, AND MAKE WE CAN

10:46AM 5 ADDRESS THIS A LITTLE LATER ON, BUT WITH RESPECT TO THE DOUBLE

10:46AM 6 HEARSAY REDACTIONS, WE UNDERSTAND THAT THE COURT'S RULING

10:46AM 7 PERMITS THE GOVERNMENT TO TRY TO LAY THE FOUNDATION TO ADMIT

10:46AM 8 THESE STATEMENTS IN THE REPORT.

10:46AM 9 WE SUBMIT THAT THEY HAVE NOT DONE SO NOW. WE ALSO SUBMIT

10:46AM 10 THAT THEY WON'T BE ABLE TO DO SO WITH RESPECT TO THESE SPECIFIC

10:46AM 11 LAB STAFF WHO WERE QUOTED IN THE REPORT.

10:46AM 12 BUT WE ALSO ACKNOWLEDGE IF THE COURT WERE TO DEFER ON ANY

10:46AM 13 ISSUE RELATED TO THIS MOTION, THIS IS THE CATEGORY WHERE IT

10:46AM 14 MIGHT MAKE SENSE.

10:46AM 15 WE ASK, HOWEVER, THAT IF THE COURT DOES DEFER ON THIS

10:46AM 16 ISSUE, WE DO SO BY LEAVING THE REDACTIONS IN PLACE FOR NOW, AND

10:46AM 17 THEN WE CAN REVISIT THEM IF AND WHEN THE GOVERNMENT BELIEVES

10:46AM 18 THAT IT HAS LAID THE FOUNDATION FOR THE ADMISSION OF THOSE

10:46AM 19 PARTICULAR STATEMENTS.

10:46AM 20 THE COURT: THANK YOU FOR THAT. THANKS FOR THAT

10:46AM 21 OBSERVATION. I THINK YOU'RE DOVETAILING ON THE COURT'S

10:46AM 22 INVITATION TO RAISE CERTAIN ISSUES AND CONCURRENT WITH THAT IS

10:46AM 23 WHAT IS THE TIMING FOR THAT?

10:46AM 24 AND YOU AND YOUR TEAM HAVE INDICATED, WELL, IT'S NOW. WE

10:47AM 25 WANT TO TELL YOU WHAT OUR OBJECTIONS ARE AND THESE, I THINK

10:47AM 1 YOUR TEAM IS SUGGESTING, THESE OBJECTIONS ARE DIFFERENT FROM
10:47AM 2 OUR ARGUMENTS AT THE MIL HEARING BECAUSE THAT'S WHAT I ASKED
10:47AM 3 YOU TO DO, NOT SAME ARGUMENTS BUT DIFFERENT ARGUMENTS AS TO
10:47AM 4 SPECIFIC PIECES OF EVIDENCE. THAT'S WHAT YOU'VE DONE HERE.

10:47AM 5 I APPRECIATE YOU RECOGNIZING AND USING THE WORD "DEFER."
10:47AM 6 BECAUSE IT JUST MAY BE -- WE DON'T KNOW. THE TRIAL HAS NOT
10:47AM 7 STARTED YET. THE EVIDENCE HAS NOT YET BEEN INTRODUCED. AND I
10:47AM 8 SUPPOSE THERE IS A POSSIBILITY FOR FOUNDATIONAL PRESENTATION AS
10:47AM 9 TO SOME OF THESE THINGS, I THINK YOU CONCEDE THAT AS YOU'VE
10:47AM 10 JUST SAID, FOR SOME OF THESE, POTENTIALLY ALL BUT AT LEAST SOME
10:47AM 11 OF THEM. I APPRECIATE THE OBSERVATION.

10:47AM 12 MR. LOOBY: YES. YOU KNOW, WE RAISE IT NOW BECAUSE
10:47AM 13 WE RECOGNIZE ALSO THAT THIS PRESENTS SOME DIFFICULT ISSUES, AND
10:47AM 14 THESE ARE LONG REPORTS WITH A LOT OF PROPOSED REDACTIONS.

10:47AM 15 WE SUBMIT THAT THIS IS THE TIME TO START TALKING ABOUT
10:47AM 16 THIS AND TO RAISE OUR OBJECTIONS ON IT AT THE COURT'S
10:48AM 17 INVITATION.

10:48AM 18 WE ALSO SUBMIT THAT SOME OF THEM, LIKE THE BILL OF
10:48AM 19 PARTICULARS TESTS, I MEAN, THE GOVERNMENT DIDN'T OFFER ANY
10:48AM 20 PERMISSIBLE PURPOSE. THAT'S THE BULK OF THE REDACTIONS, AND I
10:48AM 21 DON'T SEE THAT CHANGING.

10:48AM 22 SO EVEN IF THE COURT WERE TO DEFER ON ADOPTING THE ACTUAL
10:48AM 23 REDACTIONS, I THINK THE GOVERNMENT HAS NOT OFFERED A
10:48AM 24 PERMISSIBLE PURPOSE FOR THOSE.

10:48AM 25 THE COURT: AND THEY MAY NOT INTRODUCE THEM IN THEIR

10:48AM 1 CASE-IN-CHIEF FOR ALL WE KNOW.

10:48AM 2 MR. LOOBY: RIGHT. IN THEIR OPPOSITION, ONE OF
10:48AM 3 THEIR COMPLAINTS WAS, YOU KNOW, WE DIDN'T HAVE AN OPPORTUNITY
10:48AM 4 TO SAY WHICH PORTIONS OF THE REPORT WE ACTUALLY WANT TO USE AND
10:48AM 5 WHY.

10:48AM 6 YOU KNOW, IT'S -- AGAIN, I SOUND LIKE A BROKEN RECORD, BUT
10:48AM 7 TRIAL IS DAYS AWAY AT THIS POINT AND THESE ARE, YOU KNOW,
10:48AM 8 IMPORTANT PIECES OF EVIDENCE POTENTIALLY IN THE CASE. I THINK
10:48AM 9 ANY CLARITY THAT WE CAN GAIN SOONER RATHER THAN LATER WOULD
10:48AM 10 AVOID DISRUPTING THE PROCEEDINGS AND JUST MAKE EVERYTHING
10:48AM 11 SIMPLER FOR EVERYBODY.

10:49AM 12 THE COURT: OKAY. THANK YOU.

10:49AM 13 MS. VOLKAR.

10:49AM 14 MS. VOLKAR: THANK YOU, YOUR HONOR.

10:49AM 15 I WANT TO START WITH MY COLLEAGUE'S LAST COMMENT THERE
10:49AM 16 WHICH IS WE ARE DAYS AWAY FROM TRIAL AND THAT MAKES IT ALMOST
10:49AM 17 MORE ABSURD TO ME THAT PARTICULARLY WITH THIS RULING WITH THE
10:49AM 18 CMS, THIS IS NOT -- THIS IS THE MOST CLEAREST EXAMPLE OF A
10:49AM 19 MOTION TO RECONSIDER. THIS IS NOT AN INSTANCE WHERE THE COURT
10:49AM 20 INVITED FURTHER COMMENT FROM DEFENSE COUNSEL.

10:49AM 21 THEY ESSENTIALLY TOOK YOUR HONOR'S RULING WITH RESPECT TO
10:49AM 22 THE FDA AND OTHER ASPECTS OF THE MOTION IN LIMINE RULING AND
10:49AM 23 ARE TRYING TO APPLY IT TO ONE OF THE CLEAREST, MOST CRISP
10:49AM 24 STATEMENTS THAT YOU HAVE MADE IN YOUR MOTION IN LIMINE ORDER,
10:49AM 25 WHICH IS TO GRANT THE GOVERNMENT'S ADMISSION OF THE CMS REPORT

10:49AM 1 AND TO DENY THEIR REQUEST TO NOT ONLY EXCLUDE THE CMS REPORT,
10:49AM 2 BUT THE CMS LETTER WHICH WAS TALKED ABOUT FOR AT LEAST A HALF
10:49AM 3 HOUR AT THE HEARING, NOT JUST FOR RELEVANCE AND UNDUE
10:49AM 4 PREJUDICE, BUT ALSO FOR HEARSAY.

10:49AM 5 THEY'RE TRYING TO TURN YOUR HONOR'S RULING ON ITS HEAD
10:49AM 6 MERE WEEKS BEFORE TRIAL.

10:49AM 7 AND THE GOVERNMENT AND WE STRENUOUSLY OBJECT TO BOTH THE
10:50AM 8 REPLY AND TO MR. LOOBY'S SUGGESTION THAT THE PARTIES AGREE THAT
10:50AM 9 SOME REDACTIONS ARE REQUIRED.

10:50AM 10 WE ABSOLUTELY DO NOT BOTH AGREE THAT REDACTIONS ARE
10:50AM 11 REQUIRED. WE AGREE THAT YOUR HONOR MADE RULINGS IN OTHER
10:50AM 12 REGARDS, BUT YOUR HONOR CLEARLY ADMITTED THE CMS REPORT AND
10:50AM 13 WITHOUT ANY CAVEATS THAT I'M AWARE OF.

10:50AM 14 I JUST WANTED TO READ FROM YOUR HONOR'S ORDER WHICH SAYS,
10:50AM 15 "FOR THE REASONS ABOVE, THE COURT DENIES HOLMES'S MOTION TO
10:50AM 16 EXCLUDE THE EVIDENCE ARISING OUT OF THE CMS SURVEYS IN
10:50AM 17 QUESTION," THIS IS PAGE 20 OF ECF 798. "THE COURT GRANTS THE
10:50AM 18 GOVERNMENT'S MOTION TO ADMIT THE JANUARY 26TH, 2016, FORM CMS
10:50AM 19 2567 STATEMENT OF DEFICIENCIES," PERIOD.

10:50AM 20 AND, YOUR HONOR, I KNOW THAT WE'RE GOING TO TALK A BIT
10:50AM 21 ABOUT WHY I THINK THEIR OTHER OBJECTIONS DON'T HAVE MERIT, BUT
10:50AM 22 I WANT TO START WITH THAT THIS IS THE CLEAREST EXAMPLE OF A
10:50AM 23 MOTION TO RECONSIDER THE COURT'S UNEQUIVOCAL STATEMENT THAT DID
10:50AM 24 NOT INVITE FURTHER COMMENT.

10:50AM 25 WITH THE FDA REPORTS, I COMPLETELY AGREE WITH YOUR HONOR,

1 YOU INVITED FURTHER COMMENT, DEFENSE COUNSEL TOOK YOU UP ON IT,
2 BUT IN THE MEANTIME THEY'RE TRYING TO BRING INTO YOUR COMMENTS
3 ON THE FDA REPORTS A RULING THAT WAS CLEAR AND UNEQUIVOCAL ON
4 THE CMS REPORT, AND, THEREFORE, TODAY WE'RE HAVING A LOT OF THE
5 SAME DISCUSSIONS THAT WE HAD MONTHS AGO.

6 AND I WANT TO START ON THAT POINT WITH THE BILL OF
7 PARTICULARS BECAUSE ONE OF THE THINGS THAT I JUST HEARD
8 OPPOSING COUNSEL SAY IS THAT THE GOVERNMENT HAS NEVER PROVIDED
9 ANY THEORY OF RELEVANCE FOR THE ASSAYS NOT IN THE BILL OF
10 PARTICULARS, BUT THAT'S ABSOLUTELY NOT CORRECT.

11 THE GOVERNMENT PROVIDED EXACTLY THAT MULTIPLE THEORIES OF
12 RELEVANCE IN ITS OPPOSITION TO -- OR SORRY, IN ITS OPPOSITION
13 TO THE CMS REPORT AND IN CONNECTION WITH ITS MOTION IN LIMINE
14 TO ACCEPT THE MOTION IN LIMINE REPORT.

15 AND SPECIFICALLY -- ONE MOMENT, YOUR HONOR.

16 (PAUSE IN PROCEEDINGS.)

17 MS. VOLKAR: ECF 664 AT 5 THE GOVERNMENT EXPLAINED
18 HOW IT COULD BE USED FOR SHOWING NOT JUST THAT THERE WERE
19 INACCURATE AND UNRELIABLE TESTS FOR THE TESTS IN THE BILL OF
20 PARTICULARS, BUT THEY COULD ALSO SHOW THAT THERE WERE
21 DEFICIENCIES IN THERANOS'S OVERALL LAB PRACTICES AND A LACK OF
22 DOCUMENTATION ABOUT QUALITY CONTROL OR QUALITY ASSURANCE FROM
23 WHICH JURORS COULD INFER INFORMATION THAT IS RELEVANT ABOUT THE
24 TESTS.

25 AND WHAT I'M TRYING TO SAY THERE, YOUR HONOR, THERE ARE

10:52AM 1 MULTIPLE WAYS IN WHICH THIS INFORMATION IN THE CMS REPORT COULD
10:52AM 2 BE RELEVANT EVEN IF IT'S NOT TALKING ABOUT THE INACCURACY OR
10:52AM 3 UNRELIABILITY OF AN ASSAY THAT IS NOT ON THE BILL OF
10:52AM 4 PARTICULARS.

10:52AM 5 AND I SAY THIS, AND I'M ACTUALLY GENUINELY SURPRISED ABOUT
10:52AM 6 OPPOSING COUNSEL'S ASSISTANCE ON THIS BECAUSE THIS WAS DEBATED
10:53AM 7 FOR HOURS AT THE MOTION IN LIMINE HEARING. AND YOUR HONOR
10:53AM 8 THOROUGHLY AND THOUGHTFULLY WENT THROUGH THIS AND DECIDED IN
10:53AM 9 THE GOVERNMENT'S FAVOR THAT, YES, THIS WAS.

10:53AM 10 AND JUST AS AN EXAMPLE, AND I THINK YOUR HONOR WAS LOOKING
10:53AM 11 AT THIS, IF YOU LOOK AT THE FIRST FIVE PAGES OF THE CMS REPORT,
10:53AM 12 WHICH IS PAGE 6, 898-6 THAT YOU WERE REFERRING TO, IS ENTIRELY
10:53AM 13 HIGHLIGHTED. AND THERE ARE PAGES AND PAGES AND PAGES OF THE
10:53AM 14 126 PAGE REPORT THAT ARE JUST ENTIRELY HIGHLIGHTED AND
10:53AM 15 REDACTED.

10:53AM 16 AND AS I STATED IN MY OPPOSITION TO THEIR MOTION TO
10:53AM 17 RECONSIDER, WHAT THEY SEEK TO DO IS TURN THE GOVERNMENT'S --
10:53AM 18 I'M SORRY, TO TURN THE COURT'S MOTION IN LIMINE GRANTING THE
10:53AM 19 GOVERNMENT'S -- I'M SORRY, THE COURT'S ORDER GRANTING THE
10:53AM 20 GOVERNMENT'S MOTION IN LIMINE TO INCLUDE THE CMS REPORT INTO
10:53AM 21 INCLUDING LESS THAN 15 PERCENT, LESS THAN A QUARTER OF THAT
10:53AM 22 REPORT.

10:53AM 23 THEY WANT TO TURN THE COURT'S ORDER ENTIRELY ON ITS HEAD
10:53AM 24 AND EXCLUDE THREE-QUARTERS OF THE REPORT AND MOST ANYTHING THAT
10:54AM 25 ACTUALLY RELATES TO WHAT THERANOS WAS OR WASN'T DOING IN THE

10:54AM 1 EYES OF CMS.

10:54AM 2 SO I JUST WANT TO STRENUOUSLY PUT FORTH THE GOVERNMENT'S
10:54AM 3 POSITION THAT OUT OF ALL OF THE MOTIONS, THIS ONE IS THE MOST
10:54AM 4 OBVIOUSLY A MOTION TO RECONSIDER WHERE THE COURT PREVIOUSLY
10:54AM 5 WAS.

10:54AM 6 THE COURT: ALL RIGHT. THANK YOU.

10:54AM 7 MR. LOOBY: SO, YOUR HONOR, ON THE HEARSAY POINT IN
10:54AM 8 PARTICULAR, IN THE COURT'S ANALYSIS IN ITS IN LIMINE RULING AND
10:54AM 9 IT INCORPORATED THE DISCUSSION OF THE HEARSAY ISSUES FROM THE
10:54AM 10 FDA REPORT, AND THAT'S WHERE THE COURT OBSERVED THAT THERE ARE
10:54AM 11 SOME OBSERVATIONS IN THE FDA INSPECTION DOCUMENTS THAT GO
10:54AM 12 BEYOND MERE ANALYSIS, AND WE SUBMIT A MERE FACTUAL OBSERVATIONS
10:54AM 13 TO INCLUDE THE HIGH LEVEL ANALYSIS AND THAT THOSE MIGHT NOT BE
10:54AM 14 ADMISSIBLE UNDER THE HEARSAY RULE.

10:54AM 15 WE SUBMIT THE SAME IS TRUE WITH THE CMS REPORT.

10:54AM 16 AND I THINK THE OTHER THING ABOUT MY FRIEND'S ARGUMENT IS
10:55AM 17 THAT, YES, YOUR HONOR ADMITTED THE CMS REPORT ITSELF, BUT
10:55AM 18 YOUR HONOR ALSO EXCLUDED EVIDENCE RELATING TO ACCURACY AND
10:55AM 19 RELIABILITY OF TESTS NOT AT ISSUE IN THE BILL OF PARTICULARS.

10:55AM 20 IF YOU GO TO THAT FIRST DEFICIENCY ON PAGE 6 OF 898-6
10:55AM 21 BECAUSE WE WERE ALL THERE, IF YOU LOOK AT WHY IT'S COMPLETELY
10:55AM 22 IRRELEVANT AND JUSTIFIABLY REDACTED, THE CONTENT OF IT IS THAT
10:55AM 23 THE LABORATORY WAS ENROLLED IN A COLLEGE OF AMERICAN
10:55AM 24 PATHOLOGIST PT PROGRAM FOR THIS SPECIFIC ASSAY ALKALINE
10:55AM 25 PHOSPHATE, ALPTPPT, AND THAT THEY HAD A NONGRADED RESULT THAT

10:55AM 1 NEEDED TO BE INVESTIGATED.

10:55AM 2 I DON'T SEE HOW THIS IS RELEVANT TO ANY OF THE THEORIES
10:55AM 3 THAT THE GOVERNMENT HAS PUT FORWARD, AND SO WE PROPOSE THAT
10:56AM 4 THESE OBSERVATIONS BE REDACTED.

10:56AM 5 AND I HAVEN'T HEARD ANY RELEVANCE THEORY THAT WOULD MAKE
10:56AM 6 THIS AN ISSUE IN THE CASE.

10:56AM 7 THE COURT: LOOKING AT THAT SAME PAGE, IT LOOKS LIKE
10:56AM 8 PARAGRAPH OR ITEM D, IS THAT THE HEARSAY OR AN EXAMPLE OF THE
10:56AM 9 HEARSAY THAT YOU THINK IS OBVIOUS HERE?

10:56AM 10 MR. LOOBY: YES, YOUR HONOR.

10:56AM 11 SO THIS ONE IS CODED A, B, AND C BECAUSE IT CONTAINS
10:56AM 12 WITHIN IT ALL OF THE DIFFERENT REDACTIONS. SO IT'S COMPLETELY
10:56AM 13 IRRELEVANT BECAUSE IT RELATES EXCLUSIVELY TO A TEST NOT AT
10:56AM 14 ISSUE.

10:56AM 15 AND I WILL SAY, YOUR HONOR, WE DIDN'T REDACT OBSERVATIONS
10:56AM 16 THAT RELATED TO LAB PRACTICES THAT COULD POTENTIALLY IMPACT
10:56AM 17 OTHER TESTS. LIKE, FOR EXAMPLE, THERE ARE OBSERVATIONS ABOUT
10:56AM 18 FREEZER TEMPERATURES. SO WHERE WE COULDN'T DETERMINE
10:56AM 19 ABSOLUTELY THAT THIS DOESN'T RELATE TO A TEST NOT AT ISSUE, WE
10:56AM 20 PROPOSED TO LEAVE THOSE UNREDACTED, EVEN THOUGH THE CONNECTION
10:56AM 21 BETWEEN THAT AND ANY ISSUE IN THE CASE IS A LITTLE TENUOUS IN
10:56AM 22 MY OPINION.

10:56AM 23 YOU KNOW, WE WERE CONSERVATIVE IN REDACTING FOR WHAT IS
10:56AM 24 NOT AT ISSUE IN THE CASE. THE FACT THAT IT'S A SUBSTANTIAL
10:57AM 25 PORTION OF THE REPORT, I MEAN IT -- LIKE I SAID BEFORE, IT'S AN

10:57AM 1 AUDIT OF THE ENTIRE LABORATORY PRACTICE AND DIFFERENT TESTS
10:57AM 2 EACH HAVE THEIR OWN FINDINGS, AND THERE ARE CERTAIN TESTS THAT
10:57AM 3 ARE NOT AT ISSUE IN THE CASE. THERE A LOT OF TESTS THAT ARE
10:57AM 4 NOT AT ISSUE IN THE CASE.

10:57AM 5 THE COURT: I UNDERSTAND.

10:57AM 6 THIS GETTING BACK TO THIS D, IT SAYS, "THE GENERAL
10:57AM 7 SUPERVISOR STATED THAT THE QUALITY CONTROL," ET CETERA. THAT'S
10:57AM 8 THE HEARSAY PORTION?

10:57AM 9 MR. LOOBY: YES.

10:57AM 10 THE COURT: AS WELL AS THE FOLLOWING E, "THE MANAGER
10:57AM 11 CONFIRMED"?

10:57AM 12 MR. LOOBY: YES.

10:57AM 13 THE COURT: MAYBE THAT'S NOT AS STRONG OF A HEARSAY
10:57AM 14 ISSUE, BUT THAT'S THE HEARSAY THAT YOU'RE TALKING ABOUT?

10:57AM 15 MR. LOOBY: YEAH. THEY VARY IN THE WAY THAT THEY
10:57AM 16 DESCRIBE THE INFORMATION ORALLY RELAYED FROM THE LAB STAFF, BUT
10:57AM 17 IT'S ALL -- THE BASIS OF THE OBSERVATIONS ARE WHAT WAS TOLD TO
10:57AM 18 THE INSPECTOR.

10:57AM 19 MS. VOLKAR: YOUR HONOR, IF I MAY? I WANT TO
10:57AM 20 RESPOND TO THAT AND ALSO TO SEVERAL COMMENTS THAT MR. LOOBY
10:57AM 21 MADE EARLIER AS WELL.

10:57AM 22 SO FIRST AND FOREMOST WITH THE DOUBLE HEARSAY, AGAIN, I GO
10:57AM 23 BACK TO THIS IS ONE OF THE CLEAREST EXAMPLES OF SOMETHING THAT
10:58AM 24 THE COURT HAS REALLY ALREADY DECIDED, AND THEY'RE JUST
10:58AM 25 ESSENTIALLY ASKING THE COURT TO RECONSIDER OR TO REVISIT ITS

10:58AM 1 PRIOR RULING.

10:58AM 2 AND WHAT DO I MEAN BY THAT? IN A PRIOR PART -- IN A
10:58AM 3 DIFFERENT PART OF YOUR ORDER AT 2527 YOU TALKED ABOUT A
10:58AM 4 DIFFERENT CMS REPORT, THE SEPTEMBER 5TH, 2015 CMS LETTER AND
10:58AM 5 FOUND THAT IT WAS SUFFICIENTLY LINKED TO MS. HOLMES TO OVERCOME
10:58AM 6 THE AGENCY CONCERNS THAT YOUR HONOR HAD FOR THE ADOPTED
10:58AM 7 ADMISSIONS.

10:58AM 8 IN THAT SAME GOVERNMENT'S OPPOSITION ECF 677, THE
10:58AM 9 GOVERNMENT TALKED ABOUT ALSO THESE SAME CMS, THE SAME
10:58AM 10 INSPECTION, HOW MS. HOLMES SHADOWED THE CMS INSPECTOR DURING
10:58AM 11 ONE OF THEM. EVERYONE SHE TALKED TO MS. HOLMES WAS THERE.

10:58AM 12 SO THE IDEA THAT THESE ARE DIFFERENT EVENTS OR THAT THE
10:58AM 13 STATEMENTS THAT MIGHT HAVE MADE THEIR WAY INTO THIS REPORT
10:58AM 14 DIDN'T HAVE MS. HOLMES ESSENTIALLY RIGHT THERE THE ENTIRE TIME
10:58AM 15 DOESN'T MAKE ANY SENSE.

10:58AM 16 AND I GO BACK TO YOUR HONOR FOUND THAT ESPECIALLY WHEN ALL
10:58AM 17 OF THESE ITEMS WERE CRYSTAL CLEAR IN EVERYONE'S MINDS MONTHS
10:59AM 18 AGO AS WE BRIEFED THIS EXTENSIVELY. YES, YOUR HONOR'S RULING
10:59AM 19 ONLY RELATED TO ONE LETTER, BUT IT EXTENDS TO THESE OTHER ITEMS
10:59AM 20 AS WELL.

10:59AM 21 AND I WOULD POSIT THAT THAT'S WHY YOUR HONOR DID FIND THAT
10:59AM 22 THERE WAS NO HEARSAY PROBLEMS WITH THE CMS REPORT WHEN YOU
10:59AM 23 DECIDED TO ADMIT IT MONTHS AGO.

10:59AM 24 AND I ALSO -- ON THAT SAME TOPIC, THE CMS LETTER THAT WE
10:59AM 25 WERE TALKING ABOUT BEFORE, THERE WAS A LENGTHY BACK AND FORTH

10:59AM 1 BETWEEN THE PARTIES AND YOUR HONOR ABOUT WHETHER OR NOT THE CMS
10:59AM 2 LETTER CONSTITUTED HEARSAY AS WELL AS RELEVANCE AND UNDUE
10:59AM 3 PREJUDICE.

10:59AM 4 AND IN YOUR HONOR'S RULING WHEN YOU SAID YOU DID NOT FIND
10:59AM 5 A HEARSAY PROBLEM, YOU TALKED ABOUT THE CMS HEARSAY FINDINGS
10:59AM 6 AND SANCTIONS. YOU DID NOT LIMIT IT JUST TO THE CMS REPORT
10:59AM 7 WHEN YOU FOUND THERE WAS NOT A HEARSAY PROBLEM.

10:59AM 8 AND SO I GO -- THEN THERE ARE, OF COURSE, REASONS FOR
10:59AM 9 THAT, WHICH, AGAIN, WE TALKED ABOUT MONTHS AGO, BUT I'M HAPPY
10:59AM 10 TO REPEAT HERE.

10:59AM 11 FOR EXAMPLE, THE CMS COVER LETTER TALKS ABOUT THE EFFECT
10:59AM 12 ON THE HEARER. WHAT DID MS. HOLMES DO IN RESPONSE TO RECEIVING
11:00AM 13 THAT LETTER THAT WAS TITLED IMMEDIATE JEOPARDY.

11:00AM 14 WHAT WAS THE NEXT STEPS THAT THERANOS HAD TO TAKE IN A
11:00AM 15 LEGAL OBLIGATION WAY TO RESPOND TO AND REACT TO THAT?

11:00AM 16 AGAIN, I'M TRYING TO REPEAT ARGUMENTS THAT I KNOW
11:00AM 17 YOUR HONOR HAS ALREADY HEARD, BUT AT THE SAME TIME THIS HAS
11:00AM 18 BEEN DISCUSSED VERY THOROUGHLY, AND I GUESS THE GOVERNMENT'S
11:00AM 19 POSITION AT THE SIMPLEST IS THAT THIS HAS ALREADY BEEN
11:00AM 20 DISCUSSED AND DECIDED.

11:00AM 21 THE LAST PART THAT I WANTED TO TALK ABOUT WAS THE FDA
11:00AM 22 REPORTS. AND I JUST WANTED TO SAY THAT THE GOVERNMENT AGREES
11:00AM 23 WITH YOUR HONOR, THEY SAY OBSERVATIONS. THE SENTENCE THAT
11:00AM 24 THEY'RE SEEKING TO REDACT DOESN'T REALLY MAKE SENSE COMPARED TO
11:00AM 25 WHAT FOLLOWS BY THE WORD "SPECIFICALLY," AS YOU POINTED OUT.

11:00AM 1 BUT REALLY THE CMS REPORT IS THE ONE THAT WE UNDERSTAND
11:00AM 2 YOUR HONOR INVITED FURTHER COMMENT ON THE FDA REPORTS.

11:01AM 3 THE CMS REPORT WE JUST THINK WE'RE SURPRISED WE'RE HERE
11:01AM 4 TODAY DISCUSSING IT GIVEN HOW CLEAR YOUR HONOR'S RULING WAS AND
11:01AM 5 HOW THOROUGHLY THE PARTIES DISCUSSED EXACTLY THESE ISSUES MERE
11:01AM 6 MONTHS AGO.

11:01AM 7 THE COURT: ALL RIGHT. THANK YOU.

11:01AM 8 MR. LOOBY: YES, YOUR HONOR. AND I'LL BE BRIEF.
11:01AM 9 JUST TWO POINTS.

11:01AM 10 THE FIRST ONE RELATING TO THE SEPARATE LETTER CONVEYED
11:01AM 11 FROM MR. BALWANI TO CMS THAT THE COURT HAD RULED -- WE HAD
11:01AM 12 MOVED TO EXCLUDE THAT. IT WAS DISCLOSED AS 404(B) EVIDENCE,
11:01AM 13 AND WE HAD MOVED TO EXCLUDE IT AS IRRELEVANT AND ALSO
11:01AM 14 INSUFFICIENTLY TIED TO MS. HOLMES UNDER 401 AND 404(B).

11:01AM 15 AND THE COURT'S RULING THAT IT WAS SUFFICIENTLY LINKED
11:01AM 16 BECAUSE IT'S A RELEVANCE RULING, IT'S NOT AN AGENCY RULING THAT
11:01AM 17 EVERY LAB STAFF INVOLVED IN THE CMS AUDIT WHO WERE SPOKEN TO BY
11:01AM 18 THE CMS INSPECTORS, WHO WERE INVOLVED IN ANY WAY IN THE
11:01AM 19 LABORATORY WERE MS. HOLMES'S AGENTS.

11:01AM 20 MORE SPECIFICALLY, WE ALSO DISCUSSED WHETHER OR NOT
11:02AM 21 GENERALLY AGENTS OR EMPLOYEES OF THERANOS WERE AGENTS OF
11:02AM 22 MS. HOLMES OR THE COMPANY, AND THE COURT DEFERRED AND DENIED
11:02AM 23 THE GOVERNMENT'S REQUEST TO FIND THAT AT THAT TIME.

11:02AM 24 THE CMS LETTER FROM MR. BALWANI, THE LETTER FROM
11:02AM 25 MR. BALWANI TO CMS DOESN'T PROVIDE THAT LINK. IT DOESN'T EVEN

11:02AM 1 COME CLOSE IN MY OPINION.

11:02AM 2 SO I THINK THAT THAT -- WHETHER OR NOT THE GOVERNMENT CAN
11:02AM 3 LAY THE FOUNDATION FOR THE AGENCY LINK BETWEEN MS. HOLMES AND
11:02AM 4 THE SPECIFIC EMPLOYEES THAT ARE QUOTED IN THE CMS REPORT IS
11:02AM 5 UNRESOLVED AS OF NOW UNDER THE COURT'S PRIOR RULINGS.

11:02AM 6 AND THEN FINALLY, WITH REGARD TO THE CMS COVER LETTER. I
11:02AM 7 UNDERSTAND IN OUR OPPOSITION WE HAD DEFINED THE COVER LETTER
11:02AM 8 AND THE REPORT COLLECTIVELY AND THAT WE HAD DISCUSSED THE COVER
11:02AM 9 LETTER AND THE REPORT TOGETHER HERE ON DIFFERENT BALANCES OF
11:02AM 10 RELEVANCE, UNFAIR PREJUDICE, HEARSAY, THE GAMUT.

11:03AM 11 BUT WHAT I DON'T HEAR FROM THE GOVERNMENT IS ANY
11:03AM 12 EXPLANATION FOR WHY IT FITS UNDER RULE 803(8) (A) OTHER THAN
11:03AM 13 JUST TRYING TO SAY THAT THE COURT HAS ALREADY DECIDED THIS.

11:03AM 14 WE DON'T READ THE COURT'S ORDER THAT WAY. YOUR HONOR
11:03AM 15 KNOWS WHAT IT HELD AND DIDN'T HOLD. AND SO IF THAT'S THE CASE,
11:03AM 16 WE WOULD SUBMIT THAT THE GOVERNMENT HAS MADE NO STRONG ARGUMENT
11:03AM 17 FOR WHY IT SHOULD BE ALSO ADMITTED BECAUSE IT IS AN
11:03AM 18 OUT-OF-COURT STATEMENT THAT THE COURT PURPORTS TO OFFER FOR ITS
11:03AM 19 TRUTH.

11:03AM 20 MS. VOLKAR: YOUR HONOR, IF I MAY?

11:03AM 21 I WANT TO GO BACK TO -- I HEARD MR. LOOBY SAY THAT THEY
11:03AM 22 WERE CONSERVATIVE IN THEIR REDACTIONS, AND I THINK IT'S THE
11:03AM 23 GOVERNMENT'S CLEAR POSITION THAT IT JUST DEFIES LOGIC THAT YOU
11:03AM 24 CAN BE CONSERVATIVE IN YOUR REDACTION AND SEEK TO REDACT
11:03AM 25 THREE-QUARTERS OF A REPORT.

11:03AM 1 THE GOVERNMENT BELIEVES THAT TO THE EXTENT THAT THEIR
11:03AM 2 CONCERNS HAVE ANY MERIT, YOUR HONOR CAN COVER THIS BY A
11:03AM 3 LIMITING INSTRUCTION.

11:03AM 4 BUT I THINK AS FAR AS THE HEARSAY POINT GOES, WE HAVE
11:04AM 5 EXPLAINED HOW THIS FITS UNDER THE RELEVANT RULE. WE'VE
11:04AM 6 EXPLAINED IT AT LENGTH IN THE MOTION IN LIMINE HEARING PROCESS,
11:04AM 7 AND YOUR HONOR, AGAIN, MAYBE I'M READING TOO MUCH INTO YOUR
11:04AM 8 RULING, BUT YOUR HONOR THOROUGHLY WENT THROUGH IT AND SIDED
11:04AM 9 WITH THE GOVERNMENT ESPECIALLY WITH RESPECT TO THE CMS
11:04AM 10 REPORT.

11:04AM 11 AND WE PUT FORTH THAT BECAUSE OF THE LENGTHY DISCUSSION
11:04AM 12 ABOUT THE CMS LETTER, YOUR HONOR ALSO REACHED THAT SAME
11:04AM 13 CONCLUSION WITH THE CMS LETTER IN DENYING THEIRS.

11:04AM 14 AND IF WE'RE WRONG ABOUT THAT, WE'RE HAPPY TO PROVIDE MORE
11:04AM 15 REASONS WHY WE THINK THAT IT FITS WITHIN THE HEARSAY EXCEPTION,
11:04AM 16 BUT WE JUST THINK THAT THEY READ IT TOO BROADLY.

11:04AM 17 THE COURT: WHAT LIMITING INSTRUCTION WOULD YOU
11:04AM 18 SUGGEST?

11:04AM 19 MS. VOLKAR: WELL, SPECIFICALLY -- SO THEY'VE
11:04AM 20 POINTED OUT THAT THE MAJORITY OF THEIR REDACTIONS RELATE TO
11:04AM 21 ASSAYS THAT ARE NOT IN THE BILL OF PARTICULARS. AND WE THINK
11:04AM 22 THAT AN EASY SOLUTION IN ADMITTING THIS REPORT IS THAT TO THE
11:04AM 23 EXTENT THAT ANY OF THE PORTIONS TALK ABOUT ASSAYS THAT ARE NOT
11:04AM 24 IN A LIST WE CAN PROVIDE THEM OR A LIST THAT THE COURT COULD
11:05AM 25 READ OFF, YOU'RE NOT TO TAKE ANY STATEMENTS IN THE REPORT AS

11:05AM 1 STATING THAT THOSE WERE INACCURATE OR UNRELIABLE TESTS.

11:05AM 2 THE GOVERNMENT IS HERE TO PROVE THAT THERANOS HAD
11:05AM 3 INACCURATE OR UNRELIABLE TESTS IN THESE ASSAYS. AND WE CAN
11:05AM 4 CRAFT LANGUAGE PERHAPS A LITTLE BIT MORE COHERENT THAN THAT
11:05AM 5 WITH SOME TIME, BUT THE GENERAL IDEA BEING THAT WHEN IT TALKS
11:05AM 6 ABOUT LACK OF DOCUMENTATION OR NOT HAVING QC POLICIES OR
11:05AM 7 QC PROTOCOLS, THAT MIGHT BE AN INDICATION THAT THE LAB WAS NOT
11:05AM 8 VERY WELL RUN, BUT THAT DOESN'T NECESSARILY BY IN AND OF ITSELF
11:05AM 9 MEAN THAT AN ASSAY THAT IS NOT ON THE BILL OF PARTICULARS WAS
11:05AM 10 INACCURATE OR UNRELIABLE, AND THE GOVERNMENT IS NOT SEEKING TO
11:05AM 11 PROVE THAT.

11:05AM 12 SO ANOTHER WAY OF SAYING WHAT I'M SAYING IS THAT THE
11:05AM 13 GOVERNMENT IS ABIDING BY THE COURT'S RULING ON THE BILL OF
11:05AM 14 PARTICULARS, BUT THAT ISN'T A REASON TO REDACT AS MUCH AS THEY
11:05AM 15 SEEK TO REDACT FROM THIS REPORT WHEN A LIMITING INSTRUCTION
11:05AM 16 COULD EASILY CURE IT AND ANY CONCERNS THAT THEY HAVE.

11:05AM 17 THE COURT: ONE THING I DO WANT TO SAY, MR. LOOBY,
11:06AM 18 BEFORE YOU SPEAK TO THIS, I DO HAVE SOME CONCERN ABOUT THE
11:06AM 19 ADMISSION OF EVIDENCE OF A VIOLATION OF A CIVIL REGULATION AND
11:06AM 20 WHETHER OR NOT, OR WHETHER THAT'S GOING TO BE USED IN THE
11:06AM 21 GOVERNMENT'S CASE-IN-CHIEF TO ARGUE A CRIMINAL VIOLATION.

11:06AM 22 WE ALL KNOW THAT'S NOT PERMITTED.

11:06AM 23 AND SO I WANT TO DRAW CAUTION TO EVERYONE. THAT'S WHERE I
11:06AM 24 THINK PERHAPS A LIMITING INSTRUCTION MIGHT BE NEEDED SHOULD
11:06AM 25 THAT COME UP, AND I ADVISE EVERYONE TO PAY ATTENTION TO THAT,

1 OR TO OTHERWISE, AS EVIDENCE EVOLVES OR IS INTRODUCED, THAT THE
2 PARTIES PAY ATTENTION TO THAT. I DON'T WANT THAT CONCEPT TO BE
3 OVERLOOKED.

4 IT MAY BE THAT I'LL INVITE YOU TO THINK ABOUT WHAT TYPES
5 OF INSTRUCTIONS WOULD BE APPROPRIATE AT THE TIME THAT THAT
6 EVIDENCE IS INTRODUCED THAT THE JURY SHOULD KNOW ABOUT.

7 MS. VOLKAR: THE GOVERNMENT IS HAPPY TO COMPLY WITH
8 THAT, YOUR HONOR. THANK YOU.

9 MR. LOOBY: AND JUST ONE FINAL WORD ON THAT,
10 YOUR HONOR, WHICH IS THAT THE COURT'S ORDER ON THE TEST NOT IN
11 THE BILL OF PARTICULARS PUTS THE ONUS ON THE GOVERNMENT TO
12 ARTICULATE A PERMISSIBLE PURPOSE OF RELEVANCE. AND WHAT I
13 UNDERSTAND THE GOVERNMENT TO SAY IS THAT THESE OTHER PORTIONS
14 OF THE REPORT MIGHT SHOW THAT THERE WERE POOR LAB PRACTICES.

15 WE SUBMIT THAT THAT'S NOT RELEVANT AND IS ACTUALLY
16 ESPECIALLY PREJUDICIAL FOR THE REASON THAT YOU JUST
17 ARTICULATED, YOUR HONOR, WHICH IS THAT MS. HOLMES IS NOT ON
18 TRIAL FOR RUNNING A LAB THAT WAS IN VIOLATION OF THE CLIA
19 REGULATIONS, AND SO PUTTING BEFORE THE JURY EVEN WITH A
20 LIMITING INSTRUCTION A BIG THICK REPORT THAT PRIMARILY RELATES
21 TO THAT AND THAT IS THE PRIMARY RELEVANCE THEORY I THINK IS
22 VERY PROBLEMATIC, AND SO WE WOULD SUBMIT THAT THE REDACTIONS
23 ARE THE MORE APPROPRIATE PATH.

24 THE COURT: OKAY. ALL RIGHT. THANK YOU VERY MUCH.

25 MS. VOLKAR: THANK YOU, YOUR HONOR.

11:07AM 1 THE COURT: YOU'RE WELCOME.

11:08AM 2 NOW LET'S TURN TO 912. I THINK THAT IS THE ONLY MOTION
11:08AM 3 LEFT. THIS IS MS. HOLMES'S MOTION TO STRIKE DR. DAS, I
11:08AM 4 BELIEVE.

11:08AM 5 (PAUSE IN PROCEEDINGS.)

11:08AM 6 MR. WADE: GOOD MORNING, YOUR HONOR.

11:08AM 7 LANCE WADE ON BEHALF OF MS. HOLMES.

11:08AM 8 I THINK -- I JUST WANT TO BE SURE WE'RE ON THE SAME PAGE.
11:09AM 9 I BELIEVE I HAVE DOCKET 892.

11:09AM 10 THE COURT: OH, YOU MIGHT HAVE IT. I WAS REFERRING
11:09AM 11 TO ONE OF THE OTHER PLEADINGS IN REGARDS TO THAT.

11:09AM 12 MR. WADE: MAYBE ONE OF THE REPLIES.

11:09AM 13 THE COURT: YES.

11:09AM 14 MR. WADE: JUST SO THE RECORD IS CLEAR AND WE'RE ON
11:09AM 15 THE SAME PAGE.

11:09AM 16 THE COURT: IT IS CLEAR. THANK YOU.

11:09AM 17 MR. WADE: WE'RE HERE TODAY -- THANK YOU.

11:09AM 18 THIS IS NOT A RESULT OF AN INVITATION FROM THE COURT TO
11:09AM 19 OFFER ANOTHER PLEADING. THIS IS SORT OF A DE NOVO ISSUE THAT
11:09AM 20 RESULTED FROM THE GOVERNMENT'S UNTIMELY DISCLOSURE OF EXPERT
11:09AM 21 WITNESS TESTIMONY.

11:09AM 22 THE COURT: SO HERE'S -- I'M SORRY TO INTERRUPT YOU.
11:09AM 23 BUT LET ME ASK YOU TO -- THIS IS WHAT I'M INTERESTED IN: AS TO
11:09AM 24 THE NOTICE ISSUE, AND WHAT PREJUDICE, IF ANY, THAT BRINGS, WAS
11:09AM 25 THERE A NOTICE ISSUE. IF THERE WAS, WHAT IS THE PREJUDICE OF

11:09AM 1 THAT? WHAT IS THE REMEDY, VARIOUS REMEDIES FOR THAT?

11:09AM 2 I KNOW YOU TALK IN YOUR PLEADINGS ABOUT A LACK OF ABILITY
11:09AM 3 TO INVESTIGATE AND ALSO TO DO A DAUBERT TYPE OF INVESTIGATION
11:10AM 4 AND/OR HEARING.

11:10AM 5 AND I REMIND ALL OF US THAT THERE IS STILL A DAUBERT
11:10AM 6 PENDING, ISN'T THERE, IN THIS CASE? AND I'D LIKE YOU TO TALK A
11:10AM 7 LITTLE BIT ABOUT IF THERE IS A DAUBERT FOR THIS WITNESS,
11:10AM 8 ASSUMING THIS WITNESS IS BEING OFFERED AS AN EXPERT, WHETHER OR
11:10AM 9 NOT THAT DAUBERT, ONE OF THE REMEDIES MIGHT BE, SINCE WE HAVE A
11:10AM 10 DAUBERT HEARING THAT IS YET UNNOTICED, WOULD IT BE APPROPRIATE
11:10AM 11 TO CONTINUE A DAUBERT HEARING FOR THIS WITNESS, IF NEEDED, TO
11:10AM 12 THAT YET UNIDENTIFIED DATE?

11:10AM 13 THAT'S WHAT I'M -- THOSE ARE THE THINGS THAT I'M FOCUSSED
11:10AM 14 ON HERE.

11:10AM 15 AND I SUPPOSE WHEN THE GOVERNMENT GETS UP, I'M CURIOUS,
11:10AM 16 WHAT IS THIS WITNESS? IS HE AN EXPERT OR IS HE A PERCIPIENT
11:10AM 17 WITNESS?

11:10AM 18 IF HE'S JUST A PERCIPIENT WITNESS, YOU PROBABLY WOULD SIT
11:10AM 19 DOWN.

11:11AM 20 MR. WADE: IF HE WAS JUST A PERCIPIENT WITNESS,
11:11AM 21 YOUR HONOR, WE WOULDN'T HAVE FILED THE MOTION.

11:11AM 22 AND THE GOVERNMENT, TO TRY TO FORGIVE THE TARDY
11:11AM 23 DISCLOSURE, SUGGESTED JUST THAT. I HAVE YET TO -- I HAVE YET
11:11AM 24 TO HAVE A CASE WHERE WE HAVE MADE AN OBJECTION UNDER 701 AND
11:11AM 25 702 WHERE THE GOVERNMENT HASN'T SAID -- HASN'T MADE THAT

11:11AM 1 ARGUMENT.

11:11AM 2 OF COURSE, THE NINTH CIRCUIT CASE LAW ON THIS IS QUITE
11:11AM 3 CLEAR. AND WHEN THE -- WHEN THE TESTIMONY OF A PERCIPIENT
11:11AM 4 WITNESS GETS INTO THE REALM OF OFFERING A SCIENTIFIC OPINION
11:11AM 5 THAT IS BASED ON SPECIALIZED KNOWLEDGE, SCIENTIFIC TECHNICAL
11:11AM 6 KNOWLEDGE, ALGORITHMS AND THE LIKE, IT'S -- 702 APPLIES AND
11:11AM 7 RULE 16 APPLIES. AND THAT'S WHERE WE ARE HERE.

11:11AM 8 THE COURT WILL NOTE I PASSED UP AND SHARED WITH COUNSEL
11:11AM 9 EXHIBIT 1 FOR THIS HEARING, WHICH IS ECF 893-3, BUT THIS TIME
11:12AM 10 WITH THE ATTACHMENTS.

11:12AM 11 TO AVOID CRASHING THE GOVERNMENT'S COMPUTER SYSTEM, WE
11:12AM 12 DECIDED NOT TO TRY TO FILE THIS ON ECF. OF COURSE, THE
11:12AM 13 PROSECUTION HAS HAD THIS. THEY PRODUCED IT TO US.

11:12AM 14 BUT IF YOU JUST FLIP THROUGH THIS, YOU'LL SEE THAT THIS IS
11:12AM 15 THE REPORT OF DR. DAS ON JUNE 7TH, 2021. IT'S A FOUR PAGE
11:12AM 16 REPORT. AND HE OPINES WITHIN THIS ON THE ATTACHMENTS TO THE
11:12AM 17 REPORT WHICH MAKE UP ABOUT 600 PAGES OF DATA AND OTHER SUMMARY
11:12AM 18 INFORMATION THAT CONTAINS EXTENSIVE ANALYSIS.

11:12AM 19 WITHIN THAT WHEN YOU LOOK AT THE REPORT CAREFULLY, AND, IF
11:12AM 20 NECESSARY, I'D BE HAPPY TO BRING THE COURT PARAGRAPH BY
11:12AM 21 PARAGRAPH THROUGH IT, BUT I DON'T WANT TO WASTE ANYONE'S TIME,
11:12AM 22 YOU WILL SEE THAT DR. DAS DID NOT PREPARE ANY OF THESE
11:12AM 23 MATERIALS. NONE OF THEM.

11:12AM 24 THESE ARE MATERIALS THAT WERE PREPARED BY OTHERS, THEY
11:13AM 25 WERE PUT IN FRONT OF THE WITNESS BY THE GOVERNMENT, AND THEY

11:13AM 1 ASKED HIM FOR HIS INTERPRETATION AND HIS CONCLUSIONS, WHICH IS
11:13AM 2 EXACTLY THE SAME KIND OF TESTIMONY OR EXACTLY THE SAME KIND OF
11:13AM 3 PROCESS THAT YOU WOULD DO IF YOU RETAINED AN EXPERT AND ASKED
11:13AM 4 THEM TO OFFER OPINIONS.

11:13AM 5 SO WITH RESPECT TO VIRTUALLY EVERYTHING WITHIN THE
11:13AM 6 SECOND 302, IT IS, IT IS AKIN, DIRECTLY AKIN TO RETAINED EXPERT
11:13AM 7 TESTIMONY.

11:13AM 8 NOW, WITH RESPECT TO CERTAIN OTHER INFORMATION THAT THE
11:13AM 9 GOVERNMENT HAS IDENTIFIED, IT IS DEFICIENT IN THE SENSE THAT IT
11:13AM 10 DOESN'T GIVE US A SUFFICIENT BASES AND METHODOLOGY TO PREPARE
11:13AM 11 TO EXAMINE DR. DAS.

11:13AM 12 SO WITHIN THE FIRST 302 DR. DAS TALKS ABOUT SOME
11:13AM 13 CALCULATIONS THAT HE DID USING A SIGMA 6 ANALYSIS, AND THAT HE
11:14AM 14 CAME TO CERTAIN CONCLUSIONS AS A RESULT.

11:14AM 15 AND HE REFERENCES THE BASIS OF THAT, THE DOCUMENT, THAT HE
11:14AM 16 WAS SHOWN AT THE TIME, BUT WE DON'T HAVE THE DOCUMENT. SO WE
11:14AM 17 HAVE NO WAY TO ASSESS WHETHER HIS CONCLUSIONS ARE RIGHT, WHAT
11:14AM 18 HIS CONCLUSIONS TRULY MEAN. WE MAY AGREE WITH HIS CONCLUSIONS
11:14AM 19 DEPENDING UPON WHAT THE UNDERLYING INFORMATION WAS.

11:14AM 20 OF COURSE, MS. HOLMES WAS THE PERSON WHO HIRED DR. DAS TO
11:14AM 21 COME IN AND ADDRESS THESE ISSUES. SO IT MAY WELL BE THAT WE
11:14AM 22 AGREE WITH THEM. BUT WE DON'T HAVE THE BASIS TO KNOW WHAT HIS
11:14AM 23 SCIENTIFIC TESTIMONY IS GOING TO BE.

11:14AM 24 SIMILARLY, AT 893-4 IS A DOCUMENT WHICH IS A -- SOME SORT
11:14AM 25 OF DRAFT WRITING THAT WAS BEING PREPARED WITHIN THE COMPANY

11:14AM 1 THAT MAY HAVE BEEN PREPARED BY DR. DAS.

11:14AM 2 WE DON'T KNOW REALLY WHAT THIS DOCUMENT IS OTHER THAN AT
11:15AM 3 LEAST ONE LEVEL OF HEARSAY. IT'S A HEARSAY DOCUMENT BECAUSE
11:15AM 4 IT'S NOT A FINAL DOCUMENT IN ANY RESPECT, AND THERE ARE
11:15AM 5 PROBABLY IN CERTAIN CASES MULTIPLE LAYERS OF HEARSAY WITHIN
11:15AM 6 THIS.

11:15AM 7 BUT SIGNIFICANTLY, IF THE COURT LOOKS THROUGH THIS, IT
11:15AM 8 WILL SEE REPEATED SENTENCES THAT ARE FOLLOWED BY EXHIBIT XX.
11:15AM 9 EXHIBIT XX IS MERELY A PLACEHOLDER FOR WHATEVER THE DATA WAS
11:15AM 10 THAT WOULD SUPPORT THAT CONCLUSION IN THE VIEW OF THIS EXPERT
11:15AM 11 WITNESS.

11:15AM 12 SO --

11:15AM 13 THE COURT: SO LET ME --

11:15AM 14 MR. WADE: YES.

11:15AM 15 THE COURT: I DON'T MEAN TO INTERRUPT YOU, BUT I'M
11:15AM 16 GOING TO.

11:15AM 17 I'M REALLY INTERESTED IN RULE 16 AND WHAT ROLE THAT HAS AT
11:15AM 18 ALL IN YOUR REQUEST.

11:15AM 19 MR. WADE: RULE 16 IS AT THE HEART OF THE REQUEST,
11:15AM 20 YOUR HONOR, BECAUSE EVERYTHING --

11:15AM 21 THE COURT: THAT'S WHAT I'D LIKE YOU TO TALK ABOUT.

11:15AM 22 MR. WADE: YEAH. BECAUSE EVERYTHING THAT I JUST
11:15AM 23 IDENTIFIED IN CONNECTION WITH THAT IS MATERIAL THAT WOULD NEED
11:15AM 24 TO BE IDENTIFIED UNDER RULE 16.

11:15AM 25 THE GOVERNMENT PUSHES -- THE GOVERNMENT BASICALLY MAKES NO

11:16AM 1 SUBSTANTIVE DISCLOSURE WITH RESPECT TO DR. DAS.

11:16AM 2 THE COURT: TELL ME A TIMELINE.

11:16AM 3 MR. WADE: I'M SORRY?

11:16AM 4 THE COURT: TIMELINE?

11:16AM 5 MR. WADE: A TIMELINE OF THESE DISCLOSURES? OH,
11:16AM 6 SURE.

11:16AM 7 THE GOVERNMENT PRODUCED AN INTERVIEW THAT THEY CONDUCTED
11:16AM 8 ON FEBRUARY 1ST, 2021.

11:16AM 9 THE COURT: AND WHAT I'M SPECIFICALLY INTERESTED IN,
11:16AM 10 AND I'M JUST GIVING FAIR WARNING TO THE GOVERNMENT, I HAVE SOME
11:16AM 11 CONCERNS ABOUT THE RULE 16 DISCLOSURE, AND I'D LIKE TO KNOW
11:16AM 12 WHAT ARE THE TIMELINES FOR THE DISCLOSURE, THE NOTICE OF
11:16AM 13 DISCLOSURE AS AN EXPERT. THAT'S REALLY WHAT I'M FOCUSSED ON.

11:16AM 14 I THINK I UNDERSTAND ALL OF THE THINGS THAT THIS WITNESS
11:16AM 15 WOULD PROVIDE AS AN EXPERT WITNESS. I UNDERSTAND THAT.

11:16AM 16 I'M GOING TO ASK MS. VOLKAR WHETHER OR NOT THIS IS AN
11:16AM 17 EXPERT WITNESS OR A PERCIPIENT WITNESS. THERE'S A DIFFERENCE.

11:16AM 18 AND THERE'S ACTUALLY -- THE REAL ISSUE IS WHAT THE
11:17AM 19 TESTIMONY IS, ISN'T IT, NOT WHAT TYPE OF WITNESS IT IS, IT'S
11:17AM 20 WHAT THE TESTIMONY OF THE WITNESS WILL BE.

11:17AM 21 BUT IF IT'S AN EXPERT, THEN I KNOW WE HAVE SOME -- RULE 16
11:17AM 22 GIVES US SOME GUIDANCE. THAT'S WHAT I'M FOCUSSED ON, MR. WADE.
11:17AM 23 SO DO YOU WANT TO SHARE WITH ME YOUR THOUGHTS ON IT?

11:17AM 24 MR. WADE: I BELIEVE IT GOES TO THE REMEDIES WHICH
11:17AM 25 WAS ONE OF THE TWO QUESTIONS THAT I WAS GOING TO GET TO NEXT.

11:17AM 1 SO, YES, I WILL.

11:17AM 2 THE DISCLOSURE OF DR. DAS AS A WITNESS OF ANY KIND, SO NOT
11:17AM 3 AN EXPERT WITNESS, BUT HE WAS NOT ADDED TO THE WITNESS LIST
11:17AM 4 UNTIL JUNE 3RD.

11:17AM 5 WE THEN RECEIVED WHAT THE GOVERNMENT SUGGESTS IS AN EXPERT
11:17AM 6 DISCLOSURE ON JULY 29TH, 2021. THAT'S EXHIBIT A TO OUR MOTION.
11:17AM 7 YOU CAN SEE THE EMAIL.

11:17AM 8 IT'S NONSUBSTANTIVE. IT DOESN'T SAY ESSENTIALLY ANYTHING.
11:17AM 9 IT JUST POINTS TO A VARIETY OF THINGS, INCLUDING THE DOCUMENTS
11:17AM 10 THAT I'VE IDENTIFIED, THE REPORTS, AND IT POINTS TO ALL OF THE
11:18AM 11 MATERIALS UPON WHICH DR. MASTER RELIED, THEIR RETAINED EXPERT,
11:18AM 12 ALL OF THE MATERIALS TO WHICH HE RELIED UPON IN OFFERING HIS
11:18AM 13 EXPERT OPINION AS FILED ON THE DOCKET.

11:18AM 14 THERE'S NO INDICATION THAT DR. DAS HAS ACTUALLY LOOKED AT
11:18AM 15 THOSE MATERIALS ACCORDING TO THE REPORTS OF THE INTERVIEW.

11:18AM 16 AND THE GOVERNMENT ESSENTIALLY SAYS, YOU KNOW, WITHIN
11:18AM 17 THESE, YOU KNOW, THOUSANDS OF PAGES OF MATERIAL IS THE EXPERT
11:18AM 18 DISCLOSURE, WHICH IS CLEARLY DEFICIENT FOR THE REASONS THAT
11:18AM 19 I'VE JUST IDENTIFIED.

11:18AM 20 SO WE GOT THAT NOTICE ON JULY 29TH, 2021.

11:18AM 21 THE COURT: SO LET'S TALK ABOUT THE TIMELINE.

11:18AM 22 I THINK YOU DO THIS IN THE PLEADINGS, BUT I JUST WANT THE
11:18AM 23 RECORD TO BE CLEAR ABOUT THIS.

11:18AM 24 THERE WAS SOME DISCUSSION BETWEEN THE PARTIES, THAT IS YOU
11:18AM 25 AND THE GOVERNMENT, AS TO AN AGREED UPON DISCLOSURE DATE.

11:18AM 1 IS THAT CORRECT? IS THAT ACCURATE?

11:19AM 2 MR. WADE: THERE WAS, YOUR HONOR.

11:19AM 3 THE GOVERNMENT AGREED TO MAKE THEIR DISCLOSURES BY
11:19AM 4 MARCH 6TH OF 2020, APPROACHING 18 MONTHS AGO.

11:19AM 5 THE COURT: RIGHT. AND JUST WALK ME THROUGH THAT,
11:19AM 6 PLEASE, FOR THE RECORD.

11:19AM 7 WHAT HAPPENED NEXT?

11:19AM 8 MR. WADE: THE GOVERNMENT MADE THEIR DISCLOSURE ON
11:19AM 9 MARCH 6TH OF 2020 OF CERTAIN LAB DIRECTORS THAT PREVIOUSLY
11:19AM 10 WORKED AT THERANOS. THEY WERE OBVIOUSLY AWARE OF ALL OF THE
11:19AM 11 LAB DIRECTORS AT THERANOS GIVEN THEIR INVESTIGATION AND
11:19AM 12 INDICTMENT IN THIS CASE.

11:19AM 13 SINCE THEN WE HAVE SPENT THE ENSUING YEAR-PLUS PREPARING
11:19AM 14 TO EXAMINE THOSE WITNESSES, WORKING WITH EXPERTS AND WORKING TO
11:19AM 15 PREPARE TO EITHER CHALLENGE THE VALIDITY OF THE EXPERT
11:19AM 16 TESTIMONY OR TO CONFRONT THE WITNESSES AT TRIAL.

11:19AM 17 AS YOUR HONOR KNOWS, THERE WAS EXTENSIVE MOTIONS PRACTICE
11:19AM 18 STARTING LAST YEAR, I BELIEVE, AND BLENDING INTO THIS YEAR WITH
11:20AM 19 RESPECT TO DR. MASTER.

11:20AM 20 THE COURT IDENTIFIED CERTAIN DEFICIENCIES WITH RESPECT TO
11:20AM 21 DR. MASTER AND ORDERED A DAUBERT HEARING TO OCCUR. THAT
11:20AM 22 DAUBERT HEARING, FOR REASONS THAT I BELIEVE THE COURT IS AWARE
11:20AM 23 OF, WILL LIKELY HAPPEN MID TRIAL CLOSER TO WHEN DR. MASTER
11:20AM 24 WOULD TESTIFY.

11:20AM 25 AND AMIDST ALL OF THIS, WHILE THE GOVERNMENT HAS BEEN

11:20AM 1 AWARE OF THESE ISSUES AND THEY'VE BEEN AWARE OF DR. DAS FOR
11:20AM 2 FIVE YEARS, BUT THEY WERE -- THEY SPOKE TO HIM AS A WITNESS IN
11:20AM 3 I BELIEVE JANUARY OR FEBRUARY, AND THEY SPOKE TO HIM AGAIN IN
11:20AM 4 JUNE. THEY NEVER BOTHERED TO IDENTIFY AND DISCLOSE HIM AS A
11:20AM 5 WITNESS UNTIL JULY.

11:20AM 6 THE COURT: OKAY. I'M SORRY. ALL RIGHT.

11:20AM 7 SO THE MARCH DATE, AND THEN THERE WAS SOME DISCUSSION
11:20AM 8 BETWEEN YOU AND THE GOVERNMENT.

11:20AM 9 WAS THERE SOME AGREEMENT ABOUT THE GOVERNMENT AGREED TO
11:20AM 10 DISCLOSE BY JULY 29TH, I BELIEVE IT WAS?

11:21AM 11 MR. WADE: NO.

11:21AM 12 THE COURT: OKAY.

11:21AM 13 MR. WADE: THERE WAS NO AGREEMENT WITH RESPECT TO
11:21AM 14 DR. DAS AT ALL. IT CAME OUT OF LEFT FIELD.

11:21AM 15 THE COURT: WAS THERE AN AGREEMENT? MY QUESTION WAS
11:21AM 16 NOT SPECIFIC TO DR. DAS. MY QUESTION WAS, WAS THERE AN
11:21AM 17 AGREEMENT THAT DISCLOSURE WOULD BE MADE BY JULY 29TH?

11:21AM 18 MR. WADE: NOT THAT I'M AWARE OF, YOUR HONOR.

11:21AM 19 YOU MAY HAVE BEEN REFERRING TO SOME OF THE SUPPLEMENTAL
11:21AM 20 DISCLOSURES THAT RELATED TO THE DOCTORS.

11:21AM 21 THE COURT: WHAT, WHAT -- SO JUST FOCUSSED ON THIS
11:21AM 22 WITNESS.

11:21AM 23 MR. WADE: YES.

11:21AM 24 THE COURT: AND I'M TRYING TO GLEAN WHAT THE
11:21AM 25 DEADLINES WERE FOR DISCLOSURE OF EXPERTS. THAT'S REALLY THE

11:21AM 1 QUESTION I WANT TO ASK YOU.

11:21AM 2 MR. WADE: THE DEADLINES FOR DISCLOSURES OF EXPERTS
11:21AM 3 WAS MARCH OF 2020, PERIOD.

11:21AM 4 THE COURT: OKAY. OKAY.

11:21AM 5 MR. WADE: AND THIS WITNESS WAS DISCLOSED THE END OF
11:21AM 6 JULY.

11:21AM 7 THE COURT: JULY 29, 28, 29 I THINK IT WAS.

11:21AM 8 MR. WADE: JULY 29TH OF 2021.

11:22AM 9 THE COURT: AND THAT JULY 29TH DATE WAS AN
11:22AM 10 AGREED-UPON DISCLOSURE DATE THAT YOUR TEAM AND THE GOVERNMENT
11:22AM 11 ENGAGED FOR WHAT PURPOSE? WHAT WAS SUPPOSED TO BE DISCLOSED BY
11:22AM 12 JULY 29TH?

11:22AM 13 MR. WADE: THERE WAS NOT AGREEMENT THAT RELATED TO
11:22AM 14 THIS DISCLOSURE, YOUR HONOR.

11:22AM 15 THE COURT: I UNDERSTAND THAT.

11:22AM 16 BUT WAS THERE ANY AGREEMENT THAT WAS MADE THAT THE
11:22AM 17 GOVERNMENT WOULD PROVIDE DISCLOSURES BY JULY 29TH?

11:22AM 18 MS. VOLKAR: YOUR HONOR, I CAN ANSWER THAT QUESTION
11:22AM 19 IF YOU WOULD LIKE ME TO?

11:22AM 20 THE COURT: THANK YOU.

11:22AM 21 MS. VOLKAR: SO THE GOVERNMENT -- THE DEFENSE
11:22AM 22 COUNSEL ASKED THE GOVERNMENT TO DISCLOSE ANY OF THE TREATING
11:22AM 23 PHYSICIANS WITH RESPECT TO THE PATIENTS AND BECAUSE OF THE
11:22AM 24 COURT'S ORDER TALKING ABOUT GIVING THEM SUFFICIENT NOTICE AND
11:22AM 25 UNDER RULE 16 FOR EXPERT PURPOSES, THEY SENT US A LETTER ASKING

11:22AM 1 US TO DISCLOSE THAT BY JULY 30TH SO THAT WE WOULD MEET OUR
11:22AM 2 OBLIGATIONS AND MEET THE RULE 16 OBLIGATIONS WITH RESPECTS TO
11:22AM 3 THE TREATING PHYSICIANS.

11:22AM 4 AND OUR ARGUMENT IN OUR OPPOSITION IS THAT IF THAT WAS
11:22AM 5 SUFFICIENT NOTICE FOR THOSE EXPERTS, IT'S ALSO SUFFICIENT FOR
11:23AM 6 DR. DAS.

11:23AM 7 THE COURT: THAT'S WHERE I WAS GETTING TO, MR. WADE.
11:23AM 8 SORRY TO TAKE YOU DOWN A CIRCUITOUS PATH ON THAT.

11:23AM 9 I THINK YOUR ARGUMENT IS THAT WHAT MS. VOLKAR JUST
11:23AM 10 INDICATED WAS FOR SPECIFIC DOCTORS, THE ONES WE'VE TALKED ABOUT
11:23AM 11 PREVIOUSLY.

11:23AM 12 BUT WHAT I THINK YOUR ARGUMENT IS, AND HELP ME, YOUR
11:23AM 13 ARGUMENT IS, WELL, IN ADDITION TO THOSE DOCTORS, THEY ALSO
11:23AM 14 IDENTIFIED DR. DAS AT THAT TIME; IS THAT WHAT HAPPENED?

11:23AM 15 MR. WADE: IT WAS ACTUALLY A COMPLETELY SEPARATE
11:23AM 16 EVENT THAT HAD IN MANY WAYS -- AND PART OF THE REASON MAYBE I
11:23AM 17 WAS CONFUSED OR A LITTLE SLOW ON THE UPTAKE, YOUR HONOR, IS THE
11:23AM 18 DISCLOSURE OF DR. DAS REALLY HAD NOTHING TO DO WITH THE
11:23AM 19 TREATING PHYSICIANS.

11:23AM 20 THE COURT: UNDERSTOOD. THAT'S YOUR BEST ARGUMENT,
11:23AM 21 ISN'T IT?

11:23AM 22 MR. WADE: YES.

11:23AM 23 THE COURT: "WE GOT THIS INFORMATION ON JULY 29TH.
11:23AM 24 WE DIDN'T KNOW DR. DAS WAS GOING TO BE INCLUDED, AND WE WERE
11:23AM 25 SURPRISED TO HEAR ON JULY 29TH THAT THE GOVERNMENT HAS

11:23AM 1 IDENTIFIED AN EXPERT."

11:23AM 2 MR. WADE: WE WOULD HAVE BEEN SURPRISED TO RECEIVE

11:23AM 3 THIS DISCLOSURE ON JULY 29TH OF 2020 --

11:24AM 4 THE COURT: AGREED.

11:24AM 5 MR. WADE: -- GIVEN THE DEADLINE. BUT

11:24AM 6 PARTICULARLY --

11:24AM 7 THE COURT: I THINK THAT'S YOUR ARGUMENT, ISN'T IT?

11:24AM 8 MR. WADE: YES, THAT'S RIGHT.

11:24AM 9 THE COURT: THAT'S WHAT I READ IN YOUR PLEADINGS.

11:24AM 10 WE EXPECTED TO GET CERTAIN DOCTORS, THE UNIVERSE OF

11:24AM 11 DOCTORS THAT WE TALKED ABOUT THE OTHER MOTION, AND WE AGREED WE

11:24AM 12 WOULD GET IT ON THE 29TH.

11:24AM 13 THE GOVERNMENT, IN ADDITION TO THAT, PROVIDED DR. DAS AS

11:24AM 14 AN EXPERT, AND WE'RE UPSET ABOUT THAT BECAUSE THE DISCLOSURE

11:24AM 15 WAS MONTHS, MONTHS BEFORE.

11:24AM 16 MR. WADE: THAT'S RIGHT.

11:24AM 17 THE COURT: IS THAT YOUR POSITION?

11:24AM 18 MR. WADE: THAT IS OUR POSITION. IT'S CLEARLY A

11:24AM 19 TARDY DISCLOSURE, AND IT'S CLEARLY A DEFICIENT DISCLOSURE AS

11:24AM 20 WELL.

11:24AM 21 THE COURT: AS TO THE EXPERT. OKAY. AS TO AN

11:24AM 22 EXPERT.

11:24AM 23 MR. WADE: YEAH.

11:24AM 24 THE COURT: DR. DAS, AND THIS IS THE QUESTION THAT

11:24AM 25 MS. VOLKAR IS GOING TO ANSWER, WHETHER OR NOT -- WHO IS THIS

11:24AM 1 WITNESS AND WHAT IS HE.

11:24AM 2 LET ME SHIFT TO MS. VOLKAR FOR JUST A MINUTE.

11:24AM 3 MR. WADE: SURE.

11:24AM 4 THE COURT: MS. VOLKAR, THANK YOU FOR GETTING ME TO
11:24AM 5 AT LEAST TO WHERE I'M INTERESTED IN.

11:24AM 6 MS. VOLKAR: ABSOLUTELY, YOUR HONOR.

11:25AM 7 AND WITH THAT, I WANT TO TALK ABOUT WHO DR. DAS IS FOR
11:25AM 8 JUST A MOMENT, BECAUSE IT IS THE GOVERNMENT'S POSITION THAT
11:25AM 9 HE'S NOT AN EXPERT, HE IS A PERCIPIENT WITNESS.

11:25AM 10 BUT I WANT TO FIRST DIRECTLY ANSWER THE COURT'S QUESTIONS,
11:25AM 11 WHICH IS THE TIMELINE.

11:25AM 12 SO THE GOVERNMENT FIRST INTERVIEWED DR. DAS IN FEBRUARY OF
11:25AM 13 2021. THE GOVERNMENT HADN'T INTERVIEWED HIM BEFORE THAT DATE.

11:25AM 14 TWO WEEKS LATER THE GOVERNMENT INCLUDED THAT SUMMARY OF
11:25AM 15 HIS INTERVIEW IN ITS RESPONSE IN CONNECTION WITH THE MOTION IN
11:25AM 16 LIMINE ORDER AND QUOTED FROM IT. IN FACT, THE GOVERNMENT WAS
11:25AM 17 TALKING ABOUT HOW MULTIPLE LAB DIRECTORS HAD STATED THAT THE
11:25AM 18 TESTS WERE INACCURATE AND UNRELIABLE QUOTING DR. ROSENDORFF
11:25AM 19 QUOTING DR. DAS.

11:25AM 20 THEN DEFENDANT INCLUDED IN HER MATERIALS THE LETTER FROM
11:25AM 21 DR. DAS TO CMS WHICH CONTAINS A LOT OF HIS SAME STATEMENTS THAT
11:25AM 22 HE SAID TO THE GOVERNMENT IN HIS INTERVIEW.

11:25AM 23 AND THE COURT ULTIMATELY DISCUSSED THAT LETTER, THAT
11:25AM 24 APRIL 2016 LETTER TO CMS IN ITS MOTION IN LIMINE ORDER AT
11:25AM 25 PAGE 32.

1 JUNE 3RD THE GOVERNMENT PROVIDED AN AMENDED WITNESS LIST
2 AND INCLUDED DR. DAS. AND TO THE EXTENT THAT THE COURT IS
3 CURIOUS ABOUT THE DATES THAT OCCURRED IN 2020, I JUST WANT TO
4 TAKE THE COURT BACK FOR A MOMENT AND REMIND EVERYONE IN THE
5 COURTROOM THAT AT THAT MOMENT IN TIME TRIAL WAS SCHEDULED FOR
6 JULY 2020. THE GOVERNMENT WAS MEETING ITS DISCLOSURE
7 OBLIGATIONS WHEN TRIAL AT THE TIME WAS APPROXIMATELY FOUR
8 MONTHS AWAY.

9 AND, OF COURSE, THE GOVERNMENT, I'M SURE BOTH PARTIES,
10 CONTINUED WITH TRIAL PREPARATION DURING THOSE FOUR MONTHS, BUT
11 UNBEKNOWNST TO EVERYONE A GLOBAL PANDEMIC OCCURRED AND DELAYED
12 THE TRIAL DATE FOR MORE THAN A YEAR. AND HERE WE ARE.

13 SO THAT'S MY LONGWINDED WAY OF SAYING THAT THERE ARE A LOT
14 OF THINGS THAT OCCURRED FROM THAT INITIAL DISCLOSURE DATE TO
15 THE DISCLOSURE DATE THAT WE'RE TALKING ABOUT NOW, AND TO THE
16 BEST OF MY KNOWLEDGE, THERE WAS NO INTERIM REQUIREMENT FOR AN
17 UPDATED WITNESS LIST.

18 AND TO THE EXTENT THAT THEY IN THEIR REPLY, THE DEFENDANT
19 SAYS HOW COULD WE KNOW TO CHALLENGE A WITNESS WHO WAS NOT
20 DISCLOSED TO US? BUT MAYBE NOT THE VAST MAJORITY BUT A
21 SUBSTANTIAL PORTION OF THE DEFENDANT'S MOTIONS IN LIMINE
22 CHALLENGED ITEMS THAT WERE NOT YET ON THE GOVERNMENT'S OFFICIAL
23 EXHIBIT LIST OR WITNESS LIST, MOST OBVIOUSLY THE AGENCY REPORTS
24 THAT WE WERE JUST TALKING ABOUT A MOMENT AGO. THE FDA REPORTS
25 AND THE CMS REPORTS WERE NOT AT THE TIME ON THE GOVERNMENT'S

11:27AM 1 EXHIBIT LIST. IN FACT, THEY COMPLAIN ABOUT THAT IN THEIR
11:27AM 2 MOTIONS THAT ARE CURRENTLY BEFORE THE COURT.

11:27AM 3 BUT THAT DIDN'T STOP THEM FROM FILING A MOTION IN LIMINE
11:27AM 4 ABOUT IT.

11:27AM 5 THE REASON I BRING THAT IN, YOUR HONOR, IS BECAUSE DR. DAS
11:27AM 6 WAS DISCLOSED TO THEM, THE SUBSTANCE OF HIS TESTIMONY, IN
11:27AM 7 MID-FEBRUARY OF 2021, TWO WEEKS AFTER THE GOVERNMENT SPOKE TO
11:27AM 8 HIM. THE GOVERNMENT --

11:27AM 9 THE COURT: I'M SORRY TO INTERRUPT YOU, MS. VOLKAR.

11:27AM 10 SO THAT -- THE SUBSTANCE OF HIS TESTIMONY, I THINK YOU
11:27AM 11 JUST SAID, IS THAT SUFFICIENT TO PUT A PARTY ON NOTICE THAT
11:27AM 12 THIS IS GOING TO BE AN INTENDED EXPERT WITNESS?

11:27AM 13 MS. VOLKAR: WELL, YOUR HONOR, AGAIN, THE
11:27AM 14 GOVERNMENT'S POSITION IS THAT HE IS NOT AN EXPERT, BUT I WOULD
11:28AM 15 ALSO SAY THAT AT THE VERY LEAST THEY WERE ON NOTICE OF THE
11:28AM 16 SUBSTANCE OF HIS TESTIMONY.

11:28AM 17 AND I THINK THAT'S PARTICULARLY IMPORTANT IN THIS CASE
11:28AM 18 WHEN ONE OF THEIR MOTIONS IN LIMINE MOVED TO EXCLUDE PORTIONS
11:28AM 19 OF DR. ROSENDORFF, ANOTHER LAB DIRECTOR'S TESTIMONY AS LACKING
11:28AM 20 EXPERT SUPPORT.

11:28AM 21 AS I POINT OUT IN MY OPPOSITION, A LOT OF THE COMPLAINTS
11:28AM 22 THAT THE DEFENDANT RAISED IN THAT MOTION IN LIMINE COULD APPLY
11:28AM 23 EQUALLY TO DR. DAS, WHICH IS ESSENTIALLY IN HIS ROLE AS A LAB
11:28AM 24 DIRECTOR, IN HIS DAY-TO-DAY BUSINESS AS HE WAS MAKING DECISIONS
11:28AM 25 THAT THE DEFENDANT HIRED HIM TO MAKE, THOSE MAY BE BASED ON

11:28AM 1 SCIENTIFIC OR PARTICULARIZED KNOWLEDGE, AND, THEREFORE, IT
11:28AM 2 NEEDS EXPERT SUPPORT.

11:28AM 3 YOUR HONOR LARGELY SIDED WITH THE GOVERNMENT AND SAID
11:28AM 4 ACTUALLY HE'S JUST TESTIFYING AS A PERCIPIENT WITNESS AND IN
11:28AM 5 HIS LAY CAPACITY, EVEN IF IT MIGHT BE MORE THAN THE AVERAGE
11:28AM 6 PERSON MIGHT KNOW OFF THE TOP OF THEIR HEAD, BUT BASED ON HIS
11:28AM 7 KNOWLEDGE AND EXPERIENCE, HE WAS DOING HIS DAY-TO-DAY JOB.

11:28AM 8 AND I'LL POINT YOUR HONOR --

11:29AM 9 THE COURT: SO, MS. VOLKAR, IF -- AND I JUST HEARD
11:29AM 10 YOU SAY DR. DAS IS NOT BEING OFFERED BY THE GOVERNMENT AS AN
11:29AM 11 EXPERT WITNESS?

11:29AM 12 MS. VOLKAR: WELL, YOUR HONOR, AND THIS IS THE LAST
11:29AM 13 POINT THAT I HAD WANTED TO MAKE --

11:29AM 14 THE COURT: SURE.

11:29AM 15 MS. VOLKAR: -- WHICH IS OUR POSITION IS THAT HE'S
11:29AM 16 NOT AN EXPERT.

11:29AM 17 IF YOU LOOK AT THE DISCLOSURE THAT WE SENT TO THE
11:29AM 18 DEFENDANT ON JULY 29TH, 2021, WE SAID ALTHOUGH WE SUBMIT IT IS
11:29AM 19 NOT NECESSARY, AND THE GOVERNMENT SAYS WE SUBMIT IT IS NOT
11:29AM 20 NECESSARY BECAUSE WE BELIEVE DR. DAS IS TESTIFYING AS A
11:29AM 21 PERCIPIENT WITNESS, NOT AN EXPERT WITNESS, BUT WE OURSELVES
11:29AM 22 WERE PUT ON NOTICE THAT DEFENDANT WAS LIKELY TO DISAGREE WITH
11:29AM 23 US BECAUSE IN A FOOTNOTE TO THEIR JUNE 25TH, 2021 FILING
11:29AM 24 REGARDING -- CONTESTING DR. MASTER'S SUPPLEMENTAL REPORT THEY
11:29AM 25 FLAGGED, THERE'S NO WAY THAT DR. DAS COULD TESTIFY ABOUT ANY OF

11:29AM 1 THESE ITEMS THAT HE WITNESSED AS LAB DIRECTOR AT THERANOS
11:29AM 2 BECAUSE THE GOVERNMENT HAS NOT NOTICED HIM AS AN EXPERT.

11:30AM 3 SO HERE WE ARE JUNE 2021, WE, FOLLOWING THE COURT'S MOTION
11:30AM 4 IN LIMINE ORDERS, BELIEVE WE ARE EVEN MORE SECURE IN OUR BELIEF
11:30AM 5 THAT DR. DAS IS NOT AN EXPERT, WE GET NOTICE FOR THE FIRST TIME
11:30AM 6 FROM THEM THAT THEY BELIEVE THAT DR. DAS IS -- THE SUBSTANCE OF
11:30AM 7 HIS TESTIMONY, WHICH THEY'RE OBVIOUSLY AWARE OF, MIGHT BE
11:30AM 8 EXPERT TESTIMONY.

11:30AM 9 WITHIN A MONTH OF THAT, WE PROVIDED THAT DISCLOSURE OUT OF
11:30AM 10 AN ABUNDANCE OF CAUTION SAYING ALTHOUGH WE SUBMIT IT'S NOT
11:30AM 11 NECESSARY, WE ARE PROVIDING YOU YOUR RULE 16 NOTICE. IF YOU
11:30AM 12 BELIEVE THIS IS EXPERT TESTIMONY, THEN HE'S GOING TO TESTIFY
11:30AM 13 ABOUT WHAT HE SAID IN THOSE INTERVIEWS. WE DON'T BELIEVE IT IS
11:30AM 14 EXPERT TESTIMONY.

11:30AM 15 SO THAT'S MY WAY OF SAYING, YOUR HONOR, FOR THE NOTICE
11:30AM 16 POINT, THEY HAD NOTICE OF THE SUBSTANCE. AS SOON AS WE
11:30AM 17 UNDERSTOOD THAT THEY MIGHT CONSIDER IT EXPERT TESTIMONY, EVEN
11:30AM 18 IF WE DISAGREED, WE'VE PROVIDED THEM THAT NOTICE.

11:30AM 19 AND TO YOUR POINT, YOUR HONOR, WHERE IS THE PREJUDICE?
11:30AM 20 THAT IS OUR QUESTION, WHERE IS THE PREJUDICE?

11:30AM 21 THEY ALREADY FILED MOTIONS IN LIMINE ON SIMILAR TOPICS
11:30AM 22 WITH RESPECT TO DR. ROSENDORFF THAT COULD EASILY BE APPLIED OR
11:31AM 23 THEY COULD ARGUE ABOUT WHETHER THEY ARE OR ARE NOT APPLICABLE
11:31AM 24 TO DR. DAS. THERE'S A DAUBERT HEARING. THE BINDER THAT
11:31AM 25 MR. WADE BROUGHT TODAY, THOSE ARE ALSO THE MATERIALS WITH

11:31AM 1 RESPECT TO DR. MASTER. THAT'S IN PART, PART OF THE REASON WHY
11:31AM 2 THEY ASKED TO MOVE AND TO VACATE THE DAUBERT HEARING WHICH
11:31AM 3 WOULD HAVE OTHERWISE ALREADY OCCURRED WITH RESPECT TO
11:31AM 4 DR. MASTER BECAUSE THEY WANTED TIME TO GO THROUGH THOSE
11:31AM 5 MATERIALS.

11:31AM 6 WHAT I'M SUBMITTING TO YOU, YOUR HONOR, IS THAT THESE
11:31AM 7 ISSUES HAVE BEEN THERE, ARE THERE, THEY'RE VERY MUCH AWARE OF
11:31AM 8 THEM. THERE'S NO PREJUDICE WITH RESPECT TO THIS PURPORTEDLY
11:31AM 9 LATE DISCLOSURE OF DR. DAS.

11:31AM 10 NOW, WITH YOUR HONOR'S PERMISSION, I'D REALLY LIKE TO TALK
11:31AM 11 ABOUT WHY I THINK DR. DAS IS NOT AN EXPERT.

11:31AM 12 THE COURT: THAT'S MY QUESTION IS IF HE'S NOT AN
11:31AM 13 EXPERT, THEN WE DON'T HAVE TO WORRY ABOUT RULE 16 AS AN EXPERT.
11:31AM 14 WE DON'T HAVE TO WORRY ABOUT DAUBERTS, ET CETERA.

11:31AM 15 BUT WHAT WE DO HAVE TO HAVE CONCERN ABOUT, THE COURT HAS
11:31AM 16 TO BE CONCERNED ABOUT IS WHETHER OR NOT HIS TESTIMONY WILL PART
11:32AM 17 FROM THAT OF A LAY OBSERVER AND MOVE INTO MORE TECHNICAL
11:32AM 18 TESTIMONY WHERE OTHER TYPES OF EXPERTISE ANALYSIS WOULD BE
11:32AM 19 REQUIRED TO RECEIVE.

11:32AM 20 MS. VOLKAR: ABSOLUTELY, YOUR HONOR.

11:32AM 21 AND THAT'S WHERE I WANTED TO FIRST NOTE BECAUSE I DO
11:32AM 22 APOLOGIZE, IT'S NOT IN MY OPPOSITION, BUT JUST DOWN THE HALL
11:32AM 23 JUDGE FREEMAN ACTUALLY RECENTLY RULED ON A VERY SIMILAR ISSUE
11:32AM 24 WITH RESPECT TO ENGINEERS IN THE CHEN CASE, AS YOU MIGHT KNOW
11:32AM 25 IS STILL GOING ON AT THIS MOMENT IN TIME. AND THAT'S CASE

11:32AM 1 NUMBER 5-17-CR-603, ECF 291, PAGES 15 TO 16. SHE ACTUALLY
11:32AM 2 TALKS ABOUT HOW THE ENGINEERS ARE JUST TALKING ABOUT THEIR
11:32AM 3 DAY-TO-DAY ABILITIES. THEY MAY HAVE PARTICULARIZED KNOWLEDGE.
11:32AM 4 THEY'RE NOT TESTIFYING ABOUT WHETHER OR NOT IT'S A TRADE
11:32AM 5 SECRETS, THE QUESTION THAT IS AT ISSUE IN THAT CASE, BUT
11:32AM 6 THEY'RE ALLOWED TO TALK ABOUT HOW THEY CAME TO THE DECISIONS
11:33AM 7 THEY REACHED, AND WHAT THEY WERE DOING, AND HOW THEY WERE
11:33AM 8 FURTHERING THEIR DAY-TO-DAY JOB THAT THEY WERE HIRED FOR.

11:33AM 9 THE COURT: THERE ARE CASES THAT SPEAK TO THAT. WE
11:33AM 10 KNOW THAT THERE ARE NINTH CIRCUIT CASES AND OTHER CIRCUITS THAT
11:33AM 11 TALK ABOUT THAT DISTINCTION. THAT'S WHAT I SUPPOSE YOU'RE
11:33AM 12 GOING TO TELL ME NOW ABOUT WHY THIS WITNESS CAN TESTIFY AS A
11:33AM 13 LAY WITNESS AND WHETHER OR NOT THERE'S GOING TO BE CONCERNS
11:33AM 14 ABOUT EXPERTISE THAT THE COURT HAS TO POLICE OR THERE WILL BE
11:33AM 15 OBJECTIONS, THOSE TYPES OF THINGS.

11:33AM 16 WE ALL KNOW WHAT'S GOING TO HAPPEN.

11:33AM 17 MS. VOLKAR: RIGHT. THAT'S CORRECT, YOUR HONOR.

11:33AM 18 AND WE SUBMIT, AS WE PROVIDED A LITTLE BIT OF A
11:33AM 19 DESCRIPTION IN OUR OPPOSITION FOR THE COURT, THAT DR. DAS IS
11:33AM 20 GOING TO TESTIFY ABOUT HE WAS HIRED AS LAB DIRECTOR AT THERANOS
11:33AM 21 IN LATE 2015, STARTED AS A CONTRACTOR ROLE, BECAME A
11:33AM 22 FULL-FLEDGED EMPLOYEE IN 2016.

11:33AM 23 AND WHEN HE WAS INTERVIEWED BY THE DEFENDANT HOLMES AND
11:34AM 24 HER CODEFENDANT, BALWANI, HE WAS TOLD WE WANT YOU TO SORT OF
11:34AM 25 RESPOND TO SOMETHING. HE DIDN'T KNOW EXACTLY WHAT IT WAS AT

11:34AM 1 THE TIME, BUT IT TURNED OUT THEY HIRED HIM TO HELP RESPOND TO
11:34AM 2 THE CMS INVESTIGATION. AND BECAUSE OF THAT, HE WAS ONE OF THE
11:34AM 3 KEY PEOPLE THAT WAS PUT IN CHARGE OF MARSHALLING AND GETTING
11:34AM 4 THE FACTS AND RESPONDING TO CMS, AND HE ULTIMATELY CONCLUDED
11:34AM 5 THAT CMS WAS 100 PERCENT CORRECT IN ITS FINDINGS.

11:34AM 6 AND HE, IN HIS DAY-TO-DAY JOB, WAS REVIEWING WHAT THE LAB
11:34AM 7 PRACTICES WERE, HOW THE TESTS WERE BEING RUN, THE QC, AND IN
11:34AM 8 MULTIPLE DIFFERENT WAYS HE WAS TESTING WHETHER OR NOT HE
11:34AM 9 THOUGHT IT WAS UP TO PAR, AND HE, IN HIS EXPERIENCE AS SOMEONE
11:34AM 10 WHO WAS HIRED FOR THIS PURPOSE AS A LAB DIRECTOR, DETERMINED IT
11:34AM 11 DID NOT MEET EVEN THE LOWEST BAR.

11:34AM 12 AND WHEN HE WENT TO EXPLAIN THAT TO MS. HOLMES, THE CEO,
11:34AM 13 WHEN HE WENT TO TELL HIS BOSS WE NEED TO DO SOMETHING
11:34AM 14 DIFFERENTLY, HE DECIDED TO USE A SIGMA METRIC BECAUSE HE
11:34AM 15 THOUGHT IT WAS THE EASIEST WAY TO CONVEY WHAT HE SAW AS A
11:35AM 16 LARGER PROBLEM.

11:35AM 17 SO HE USED ESSENTIALLY THIS MATHEMATICAL FORMULA, AND HE
11:35AM 18 DESCRIBED EXACTLY HOW IT'S CALCULATED, IT'S ADDITION,
11:35AM 19 SUBTRACTION, AND DIVISION, AND HE SAYS BASED ON DATA THAT IS
11:35AM 20 INCLUDED IN THERANOS'S GENERATED DOCUMENTS, AND HE SAYS THIS
11:35AM 21 PRODUCES ONE NUMBER THAT HE THINKS IT'S EASY TO CONVEY WHY HE
11:35AM 22 HAD CONCERNS ABOUT THE ACCURACY OR RELIABILITY OF THE TESTS.

11:35AM 23 SO WHAT I'M TRYING TO GET AT THERE, YOUR HONOR, IS THAT
11:35AM 24 HE'S TALKING ABOUT IN HIS DAY-TO-DAY HE WAS INFORMING
11:35AM 25 MS. HOLMES ABOUT WHY AND HOW THEY SHOULD RESPOND TO CMS. HE

11:35AM 1 WAS EXPLAINING WHY AND HOW HE THOUGHT THAT THERE WERE
11:35AM 2 DEFICIENCIES IN THE LAB THAT NEEDED TO BE CORRECTED, HE WAS
11:35AM 3 TALKING ABOUT THE QUALITY CONTROL AND ANY ERRORS THAT HE SAW IN
11:35AM 4 IT.

11:35AM 5 AND ALTHOUGH ALL OF THAT MAY SOUND SCIENTIFIC TO YOU OR I
11:35AM 6 OR OTHERS IN THE COURTROOM, AT THE END OF THE DAY, HE WAS DOING
11:36AM 7 THE JOB HE WAS HIRED TO DO, AND HE WAS PASSING ON THE
11:36AM 8 INFORMATION THAT HE WAS ASKED AND HIRED TO PASS ON.

11:36AM 9 AND WHEN HE COMES TO TESTIFY, IF YOUR HONOR WANTS TO PLACE
11:36AM 10 ANY LIMITATIONS ON, FOR EXAMPLE, HOW DETAILED HE DESCRIBES
11:36AM 11 THOSE UNDERLYING PROCESSES, AT THE END OF THE DAY WHAT HE'S
11:36AM 12 GOING TO TESTIFY ABOUT IS I DID MY JOB, AS A RESULT OF DOING MY
11:36AM 13 JOB, I DETERMINED THAT THESE TESTS DID NOT MEET EVEN THE LOWEST
11:36AM 14 BAR AND I HAD TO GO TELL MY BOSS THAT. AND I NEEDED TO BE ABLE
11:36AM 15 TO EXPLAIN IT IN A WAY --

11:36AM 16 THE COURT: AND IF HE SAYS THAT WITHOUT REFERENCE TO
11:36AM 17 A SIGMA ANALYSIS, OR SOMETHING LIKE THAT, THAT'S DIFFERENT,
11:36AM 18 ISN'T IT?

11:36AM 19 IF HE SAYS MY JOB IS TO ENSURE THAT THE LAB IS OPERATING
11:36AM 20 AS REPRESENTED AND IN COMPLIANCE WITH ALL REGULATIONS, I
11:36AM 21 CHECKED X TO DO THAT, AND I LOOK AT A SPREADSHEET, FOR EXAMPLE,
11:36AM 22 THAT TELLS ME, INFORMS ME OF MY RESPONSIBILITIES, AND I GATHER
11:36AM 23 THAT INFORMATION, AND I REPORT IT TO MY BOSS.

11:37AM 24 MS. VOLKAR: I MOSTLY AGREE, YOUR HONOR.

11:37AM 25 I WOULD ALSO SUBMIT THAT THE SIGMA METRIC, MUCH LIKE

11:37AM 1 SEVERAL OF THE ITEMS THAT WE TALKED ABOUT WITH RESPECT TO
11:37AM 2 DR. ROSENDORFF IN THE MOTION IN LIMINE, THE MULTIPLEX SEEN, THE
11:37AM 3 REFERENCE RANGES, AT THE END OF THE DAY THESE ARE STILL THINGS
11:37AM 4 THAT DO NOT REQUIRE SOME ELABORATE METHODOLOGY OR DEEP
11:37AM 5 EXPLANATION, AT LEAST THAT'S THE GOVERNMENT'S POSITION. AND SO
11:37AM 6 WE BELIEVE --

11:37AM 7 THE COURT: WELL, THAT'S A QUESTION, IS IT EVERY DAY
11:37AM 8 LIFE REASONING? DOES IT REQUIRE SPECIFIC SPECIALIST REASONING?
11:37AM 9 THAT'S THE ISSUE, ISN'T IT?

11:37AM 10 AND HE MAY TESTIFY I LOOK AT THIS, I GOT THE RESULTS, PART
11:37AM 11 OF THESE RESULTS I BELIEVE ARE GENERATED BY USING SOMETHING
11:37AM 12 CALLED THE SIGMA, WHATEVER IT IS, AND NOT TESTIFY ABOUT WHAT
11:37AM 13 THE SIGMA IS. AND YOU MIGHT HAVE AN EXPERT COME IN AND SAY
11:37AM 14 THIS IS WHAT THE SIGMA IS, BUT IT DOESN'T COME THROUGH HIM.

11:37AM 15 MS. VOLKAR: YOUR HONOR, THAT'S ENTIRELY POSSIBLE.
11:37AM 16 AND IF THE COURT WERE TO RULE THAT, THE GOVERNMENT WOULD
11:38AM 17 ABSOLUTELY FOLLOW THAT, ESPECIALLY BECAUSE, OF COURSE, WE STILL
11:38AM 18 HAVE DR. MASTER THAT I KNOW WE'VE BEEN TALKING ABOUT TODAY.

11:38AM 19 BUT I DO WANT TO POINT YOUR HONOR BACK TO THE CHEN CASE
11:38AM 20 WITH JUDGE FREEMAN THAT I MENTIONED BECAUSE IN HER ORDER SHE
11:38AM 21 ACTUALLY TALKS ABOUT HOW THE ADVISORY COMMITTEE NOTES POINT OUT
11:38AM 22 THAT IT'S SPECIALIZED KNOWLEDGE THAT ONE WOULDN'T NECESSARILY
11:38AM 23 HAVE BUT NOT NECESSARILY SOMETHING THAT WAS GARNERED JUST AS A
11:38AM 24 RESULT OF BEING IN HIS OR HER POSITION WITH THE EXPERTISE THAT
11:38AM 25 THEY HAVE.

11:38AM 1 THE COURT: I THINK WE ALL UNDERSTAND THAT. PEOPLE
11:38AM 2 HAVE JOB DESCRIPTIONS, AND THEY'RE ENTITLED TO TALK ABOUT THEIR
11:38AM 3 JOB DESCRIPTIONS.

11:38AM 4 BUT IF THEY START TALKING ABOUT THINGS THAT ARE OUTSIDE,
11:38AM 5 AS THE CASES TELL US, EVERY-DAY-LIFE-TYPE SITUATIONS, THAT
11:38AM 6 BECOMES THE ISSUE THEN, WHEN DOES, WHEN DOES A NON-EXPERT
11:38AM 7 TESTIMONY MORPH INTO EXPERTISE?

11:38AM 8 AS I'VE SAID, THAT'S SOMETHING THAT WE'LL PROBABLY HAVE TO
11:38AM 9 LOOK AT HERE.

11:39AM 10 IF YOU'RE NOT OFFERING THIS WITNESS AS AN EXPERT, THEN I
11:39AM 11 EXPECT MR. WADE'S TEAM WILL RISE TO THEIR FEET IF THEY BELIEVE
11:39AM 12 THAT THE TESTIMONY MOVES INTO THE EXPERTISE LANE.

11:39AM 13 MS. VOLKAR: WELL, YOUR HONOR, IF THAT IS THE CASE,
11:39AM 14 THEN THE GOVERNMENT WOULD RESPECTFULLY REQUEST THAT DR. DAS BE
11:39AM 15 EXPLICITLY ALLOWED TO TESTIFY THAT HE RAN MULTIPLE TESTS, EVEN
11:39AM 16 IF HE DOESN'T TALK ABOUT WHAT THOSE TESTS ARE, AND HE
11:39AM 17 CONSIDERED IN MULTIPLE DIFFERENT WAYS HOW IT COULD -- WHETHER
11:39AM 18 IT WAS OR WAS NOT MEETING, AGAIN, THAT LOWEST BAR THAT HE
11:39AM 19 TALKED ABOUT, AND THAT WHEN HE DETERMINED IT WAS NOT, HE NEEDED
11:39AM 20 TO GO TELL HIS BOSS, AND HE CHOSE TO DO SO IN A WAY THAT MADE
11:39AM 21 SENSE.

11:39AM 22 THE COURT: SURE.

11:39AM 23 MS. VOLKAR: NONE OF THAT TALKED ABOUT ANY SCIENCE
11:39AM 24 PER SE, BUT WE WOULD WANT HIM TO BE ABLE TO TALK AND TESTIFY TO
11:39AM 25 THOSE FACTS WHICH IS EXACTLY WHAT HE SAID IN HIS INTERVIEWS.

11:39AM 1 THE COURT: OKAY.

11:39AM 2 MR. WADE: WHAT COUNSEL JUST DESCRIBED, YOUR HONOR,
11:39AM 3 IS AN OPINION THAT HE FORMED ON THE BASIS OF SCIENTIFIC
11:39AM 4 KNOWLEDGE IN A METHODOLOGY.

11:40AM 5 WITH ALL DUE RESPECT, THE 6 SIGMA CALCULATION, AS THE
11:40AM 6 COURT WILL LEARN DURING THIS TRIAL, IS ANYTHING BUT EASY AND IT
11:40AM 7 IS ANYTHING BUT DE RIGUEUR IN THE DAY-TO-DAY LIFE OF NEARLY
11:40AM 8 ANYONE. IT IS QUITE A COMPLICATED CALCULATION.

11:40AM 9 AND A BIG QUESTION WHEN YOU GET TO A CALCULATION LIKE THAT
11:40AM 10 IS WHAT IS THE CALCULATION SO THAT THE DEFENDANT HAS NOTICE AND
11:40AM 11 CAN CONFRONT THE WITNESS.

11:40AM 12 THE CALCULATION IS BASED UPON DATA. WE DON'T KNOW WHAT
11:40AM 13 THE DATA IS.

11:40AM 14 SO THEY WANT TO OFFER THE ULTIMATE OPINION OF THIS EXPERT,
11:40AM 15 BUT THEY DON'T WANT TO COMPLY WITH RULE 16 THAT GIVES US THE
11:40AM 16 BASIS AND THE METHODOLOGY SO THAT WE CAN SAY THAT WAS CORRECT
11:40AM 17 OR NOT CORRECT.

11:40AM 18 HE DID IT IN HIS JOB. HIS JOB, SO WE'RE CLEAR, IS A
11:40AM 19 PERCIPIENT WITNESS, HE WAS A UNIQUE PERCIPIENT WITNESS. HE
11:40AM 20 WASN'T OBSERVING THE LAB ON A PROSPECTIVE BASIS. NONE OF THE
11:41AM 21 ISSUES THAT THEY WANT TO TALK TO HIM ABOUT RELATE TO ONGOING
11:41AM 22 SORT OF FORWARD LOOKING OR PRESENT SENSE ACTIVITY.

11:41AM 23 THEY ALL RELATE TO RETROSPECTIVE ACTIVITY, HIM LOOKING AT
11:41AM 24 DATA, LOOKING AT INFORMATION, PROVIDING A SPECIALIZED
11:41AM 25 KNOWLEDGE, AND COMING TO OPINIONS.

11:41AM 1 THE SECOND 302 HE DOES WITH RESPECT TO THE SIX INCH BINDER
11:41AM 2 ON YOUR HONOR'S DESK. NONE OF THAT RELATES IN ANY WAY TO
11:41AM 3 ANYTHING THAT HE ACTUALLY DID AT THE TIME. HE'S INTERPRETING
11:41AM 4 DOCUMENTS THAT HE DIDN'T AUTHOR.

11:41AM 5 THE COURT: MR. WADE, IS IT -- IS THERE ANY WAY THAT
11:41AM 6 THIS WITNESS COULD TESTIFY AS A PERCIPIENT WITNESS IN YOUR
11:41AM 7 OPINION?

11:41AM 8 MR. WADE: HE CAN. PROBABLY I'M GUESSING 20 PERCENT
11:41AM 9 OF HIS TESTIMONY I THINK COULD COME IN.

11:41AM 10 I'D BE HAPPY -- IF THE COURT AND COUNSEL PREFER NOT TO
11:41AM 11 OFFER HIM AS AN EXPERT AND WANTS TO GO LINE BY LINE THROUGH THE
11:42AM 12 302'S AND THE EXHIBITS, I'D BE HAPPY TO POINT OUT THE EXPERT
11:42AM 13 TESTIMONY. IT'S ACTUALLY NOT THAT DIFFICULT. WHEN YOU LOOK AT
11:42AM 14 THE 302'S IT SAYS CONCLUDES OPINIONS. IT'S VERY EXPLICIT.

11:42AM 15 THE COURT: WELL, MS. VOLKAR TELLS US THEY'RE NOT
11:42AM 16 GOING TO OFFER HIM AS AN EXPERT. SHE DID THAT AS AN ABUNDANCE
11:42AM 17 OF CAUTION BASED ON A FOOTNOTE IN ONE OF YOUR PLEADINGS, AND
11:42AM 18 SHE THOUGHT OUT OF AN ABUNDANCE OF CAUTION THEY SHOULD JUST
11:42AM 19 INDICATE AS MUCH.

11:42AM 20 WHAT SHE TELLS US TODAY THIS IS NOT AN EXPERT WITNESS.
11:42AM 21 THIS IS NOT A WITNESS THAT THEY INTEND TO HAVE A 702 HEARING OR
11:42AM 22 ANY OF THOSE ANALYSES. IT'S A PERCIPIENT WITNESS.

11:42AM 23 WHAT WE'RE TALKING ABOUT NOW IS WHAT IS THE -- WHAT ARE
11:42AM 24 THE PARAMETERS FOR THAT PERCIPIENT WITNESS TESTIMONY AS OPPOSED
11:42AM 25 TO GETTING INTO THE EXPERT LANE AND STAYING IN THE PERCIPIENT

11:43AM 1 WITNESS LANE. I THINK THAT'S WHAT WE'RE TALKING ABOUT.

11:43AM 2 I'M CURIOUS WHETHER THIS IS GOING TO BE BECAUSE HE'S NOT
11:43AM 3 GOING TO BE CALLED AS AN EXPERT WITNESS BUT RATHER AS A
11:43AM 4 PERCIPIENT WITNESS, IS THIS SOMETHING THAT WE'LL HAVE TO POLICE
11:43AM 5 AS THE WITNESS TESTIFIES? IS THIS SOMETHING THAT THE
11:43AM 6 GOVERNMENT WOULD PROVIDE A PROFFER OR AN AREA, AND I'M NOT
11:43AM 7 ASKING YOU TO DO THAT, BUT PROVIDE SOME TYPE OF EVIDENCE OF
11:43AM 8 THESE ARE THE QUESTIONS THAT WE'RE GOING TO ASK? THIS IS WHAT
11:43AM 9 IT IS.

11:43AM 10 YOU'VE TOLD ME ABOUT THAT ALREADY. I HAVE SOME CONCERNS
11:43AM 11 ABOUT THE SIGMA 6, WHATEVER THAT IS. I CAN'T EVEN PRONOUNCE IT
11:43AM 12 CORRECTLY IT'S SO COMPLICATED.

11:43AM 13 SO I THINK THAT'S PROBABLY OUTSIDE THE PURVIEW OF A
11:43AM 14 REASONABLE EVERY DAY LIFE JURY PERSON. BUT I DO THINK -- LET
11:43AM 15 ME JUST CUT TO THE CHASE, I DO THINK, MR. WADE, THAT THE
11:43AM 16 WITNESS COULD TESTIFY AS A PERCIPIENT WITNESS AND NOT GET INTO
11:43AM 17 ANY OF THOSE SPECIFICS. I DO THINK THAT'S POSSIBLE.

11:44AM 18 I TALKED A LITTLE BIT ABOUT A HYPOTHETICAL WHERE THAT
11:44AM 19 MIGHT HAPPEN. THIS IS MY JOB, THIS IS WHAT I DO, I GET THE
11:44AM 20 RESULTS, I LOOK AT THE RESULTS, AND ACCORDING TO -- I COMPARE
11:44AM 21 IT TO WHATEVER IT IS, AND THAT'S NOT MY OPINION, IT'S THE
11:44AM 22 RESULTS, AND I'M REPORTING THE RESULTS. YOU KNOW, IT'S AT A
11:44AM 23 HIGH LEVEL, OF COURSE. BUT THOSE TYPES OF TESTIMONY DO NOT, IT
11:44AM 24 SEEMS, INTERFERE INTO AN EXPERT ANALYSIS.

11:44AM 25 MR. WADE: YOUR HONOR, IF WE CAN PROPERLY AVOID THE

11:44AM 1 OPINIONS AND CONCLUSIONS AND THINGS THAT HE DID BASED UPON HIS
11:44AM 2 EXPERTISE, WE'D BE HAPPY TO LIMIT IT TO THAT 20 PERCENT AND,
11:44AM 3 YOU KNOW, MOVE FORWARD.

11:44AM 4 WHAT I'M HESITANT ABOUT, YOUR HONOR, IS WE'VE GOTTEN THIS
11:44AM 5 DISCLOSURE OVER A YEAR LATE, AND COUNSEL IS RIGHT THAT THE
11:44AM 6 TRIAL HAS MOVED, BUT WE'VE ALSO ALWAYS IN THIS CASE, AS
11:44AM 7 EVERYONE KNOWS, WE CUED THOSE DISCLOSURES TO MOTIONS PRACTICE
11:44AM 8 SO THAT WE CAN PREPARE AND PRESENT EVERYTHING IN AN ORDERLY
11:45AM 9 WAY, WHICH WE'VE DONE WITH RESPECT TO ALL OF THE OTHER MATTERS
11:45AM 10 THAT HAVE GONE UP, AND WE'VE PREPARED FOR TRIAL ACCORDINGLY.

11:45AM 11 SO THIS IS, THIS IS UNQUESTIONABLY LATE.

11:45AM 12 BUT MY CONCERN IS THAT IF WE WAIT AND DEFER ON THIS, WE'RE
11:45AM 13 NOT GOING TO DRAW THE LINES THE WAY THAT WE THINK IS
11:45AM 14 APPROPRIATE, AND THEN THEY'RE GOING TO TRY TO OFFER EXPERT
11:45AM 15 TESTIMONY WITH EVEN LESS NOTICE.

11:45AM 16 SO I DO HAVE SOME -- AND IF THE COURT WANTS TO WAIT AND
11:45AM 17 JUST RULE AND DRAW THE LINES AND CALL BALLS AND STRIKES AND
11:45AM 18 THIS IS IN, THIS IS OUT, WE WILL BE WILLING TO DEFER TO THAT.

11:45AM 19 BUT I WANT TO BE MINDFUL OF THE CASES, YOUR HONOR, AS I
11:45AM 20 HEAR COUNSEL TALK. THE NINTH CIRCUIT HAS BEEN VERY CLEAR AND
11:45AM 21 AN ANALOGOUS SET OF CIRCUMSTANCES ARE THESE LAW ENFORCEMENT
11:45AM 22 AGENT CASES WHERE YOU'RE DRIVING THE CAR AND YOU'RE OBSERVING
11:45AM 23 THINGS AND THE CAR GOES FROM THIS LANE TO THAT LANE AND THAT
11:45AM 24 LANE TO THIS LANE, AND I CAN RELAY ALL OF THAT TO THE JURY AND
11:46AM 25 I CAN DO IT AND DESCRIBE IT AS AN FBI SPECIAL AGENT, ET CETERA,

11:46AM 1 ET CETERA, RIGHT?

11:46AM 2 BUT WHEN I SAY THIS MEANS SOMETHING, I CONCLUDED THIS
11:46AM 3 MEANT SOMETHING, THAT'S EXPERT TESTIMONY.

11:46AM 4 THE COURT: THAT'S FIGUEROA-LOPEZ THAT YOU'RE
11:46AM 5 TALKING ABOUT.

11:46AM 6 MR. WADE: IT IS.

11:46AM 7 THE COURT: OF COURSE WE KNOW THAT THAT WAS A
11:46AM 8 HARMLESS ERROR FINDING AT THE END, BUT THERE WAS MENTION OF
11:46AM 9 THOSE FACTS AND WHAT HAPPENED AND HOW THERE WAS A CROSSOVER OF
11:46AM 10 EXPERTISE, AND THAT'S A GOOD EXAMPLE IN THE DRUG CASES. WELL,
11:46AM 11 THIS WAS -- THE OFFICER TESTIFIED, I THINK, IN MY OPINION,
11:46AM 12 THESE ARE ACTIVITIES THAT ARE DONE BY DRUG DEALERS. IN MY
11:46AM 13 OPINION, THESE ARE THINGS THAT ARE DONE BY DRUG DEALERS,
11:46AM 14 ET CETERA, WITHOUT BEING PROPERLY, PROPERLY IDENTIFIED AS AN
11:46AM 15 EXPERT WITNESS THE COURT SO FOUND. EXACTLY.

11:46AM 16 MR. WADE: AND HIS OPINION WAS TIED TO ACTION IN
11:46AM 17 THAT CASE AS WELL, WHICH IS IMPORTANT TO REMEMBER IN HIS LINE
11:46AM 18 OF DUTY AND IN HIS JOB.

11:46AM 19 THE COURT: BASED ON TRAINING AND EXPERIENCE. HAVE
11:46AM 20 YOU EVER HEARD OF THAT BEFORE?

11:46AM 21 MR. WADE: BASED ON TRAINING AND EXPERIENCE IN HIS
11:46AM 22 LINE OF DUTY MANY OF THE SAME THINGS THAT COUNSEL WAS JUST
11:47AM 23 SPEAKING ABOUT WITH RESPECT TO DAS, AND HE TOOK ACTION BASED
11:47AM 24 UPON THAT.

11:47AM 25 THE COURT: RIGHT.

11:47AM 1 MR. WADE: SAME THING.

11:47AM 2 THE COURT: I UNDERSTAND. I THINK I GET THAT.

11:47AM 3 MS. VOLKAR: YOUR HONOR, IF I MAY BE HEARD?

11:47AM 4 SO FIRST OF ALL, I THINK PART OF THE REASON THAT WE'RE
11:47AM 5 HERE TODAY IS WHAT CONCERNS ME IN HEARING MR. WADE'S STATEMENTS
11:47AM 6 IS THAT THEY THINK ONLY 20 PERCENT OF DR. DAS'S TESTIMONY IS
11:47AM 7 GOING TO BE ADMISSIBLE.

11:47AM 8 FRANKLY, ALTHOUGH I UNDERSTAND THE STATEMENTS FROM
11:47AM 9 YOUR HONOR, THE GOVERNMENT SUBMITS THAT EVERYTHING THAT IS IN
11:47AM 10 HIS 302'S, THE INTERVIEWS OF HIM, WOULD NOT BE EXPERT TESTIMONY
11:47AM 11 AND COMPLETELY UNDERSTAND IF THE COURT DISAGREES ON THE SIGMA
11:47AM 12 POINT, FOR EXAMPLE, ALTHOUGH WE RESERVE OUR POSITION, BUT
11:47AM 13 CERTAINLY NOT DOWN TO 20 PERCENT OF WHAT HE'S GOING TO TESTIFY
11:47AM 14 ABOUT.

11:47AM 15 ALL I'M SAYING IS THAT IT DOES SEEM THAT THIS IS SORT OF
11:47AM 16 BREWING UP FOR FURTHER, FURTHER DEBATE, AND THAT SEEMS
11:47AM 17 SOMETHING LIKE CLEARER LINES NEED TO BE DRAWN AT THIS POINT IN
11:47AM 18 TIME, OR, AGAIN, ALTHOUGH THE COURT SUBMITS -- ALTHOUGH THE
11:48AM 19 GOVERNMENT SUBMITS IT'S NOT NECESSARY, WE SUBMIT THERE'S NO
11:48AM 20 PREJUDICE AND THAT THE DISCLOSURE OF HIM AS AN EXPERT WAS NOT
11:48AM 21 UNTIMELY, AND TO THE EXTENT THAT THE COURT DISAGREES, DR. DAS
11:48AM 22 COULD BE SUBMITTED FOR A DAUBERT HEARING. OF COURSE, WE HAVE
11:48AM 23 ONE THAT IS NOT YET SCHEDULED ON SIMILAR TOPICS. WE STILL
11:48AM 24 DISAGREE AND DON'T THINK THAT THEY'VE BEEN PREJUDICED IN ANY
11:48AM 25 WAY, SHAPE, OR FORM.

11:48AM 1 THEY ABSOLUTELY KNOW WHAT HE'S GOING TO TALK ABOUT. THEY
11:48AM 2 ABSOLUTELY KNOW THE BASES FOR WHAT HE'S GOING TO TALK ABOUT.
11:48AM 3 IT OVERLAPS WITH SEVERAL WITNESSES. THIS IS NOT THE FIRST TIME
11:48AM 4 THAT WE'VE BEEN TALKING ABOUT THIS.

11:48AM 5 I ACTUALLY WANTED TO POINT TO THE FIGUEROA-LOPEZ CASE THAT
11:48AM 6 YOUR HONOR HAS BEEN TALKING ABOUT. THERE THEY FOUND -- WELL,
11:48AM 7 FIRST OF ALL, THEY FOUND THAT TESTIMONY ABOUT SUSPICIOUS
11:48AM 8 BEHAVIOR DIDN'T NECESSARILY CROSS THE LINES, BUT THERE WAS
11:48AM 9 CERTAINLY TESTIMONY THAT DID NOT CROSS THE LINE.

11:48AM 10 BUT EVEN WHEN THEY FOUND A RULE 16 VIOLATION IN A CASE
11:48AM 11 WHEN THE GOVERNMENT NEVER GAVE RULE 16 DISCLOSURE, THEY HELD IT
11:48AM 12 IS HARMLESS BECAUSE RULE 16 DOES NOT REQUIRE THE EXCLUSION OF
11:49AM 13 EFFECTIVE TESTIMONY.

11:49AM 14 IF THE PERSON HAS THE EXPERTISE AND HAS THE TESTIMONY THAT
11:49AM 15 SUPPORTS HIM AS AN EXPERT, THE COURT IN THAT CASE FOUND, WELL,
11:49AM 16 HE WOULD HAVE BEEN DEEMED AN EXPERT.

11:49AM 17 I SUBMIT TO YOUR HONOR HERE THAT THAT'S EXACTLY WHAT WE'RE
11:49AM 18 LOOKING AT. DR. DAS IS AN EXPERT. THE GOVERNMENT DID NOT
11:49AM 19 UNTIMELY DISCLOSE HIM. THEY DISCLOSED HIM PROMPTLY WHEN WE
11:49AM 20 LEARNED THAT THE DEFENDANT MIGHT DISAGREE WITH US ABOUT THE
11:49AM 21 CATEGORY THAT HIS TESTIMONY CALLS INTO, THEY'VE HAD THE
11:49AM 22 SUBSTANCE OF HIS TESTIMONY FOR MORE THAN SIX MONTHS, AND,
11:49AM 23 AGAIN, THE GOVERNMENT SUBMITS THAT DR. DAS'S TESTIMONY SHOULD
11:49AM 24 BE ALLOWED IN, IN FULL AS PROPOSED.

11:49AM 25 AND IF THE COURT DOES DISAGREE WITH US, THEN PERHAPS WE

11:49AM 1 NEED TO HAVE A DAUBERT HEARING, BUT WE REALLY URGE THAT THAT'S
11:49AM 2 NOT NECESSARY. HE IS AN EXPERT, AND HE IS QUALIFIED TO TALK
11:49AM 3 ABOUT THESE TOPICS.

11:49AM 4 THE COURT: BUT YOU -- WHAT I HEARD YOU SAY
11:49AM 5 THOUGH -- I'M SORRY, MS. VOLKAR. JUST SO I CAN GET CLARITY,
11:49AM 6 YOU'RE NOT -- IT'S NOT YOUR INTENT TO -- YOU DON'T BELIEVE THAT
11:49AM 7 YOU NEED TO OFFER HIM AS AN EXPERT, AND IT SOUNDS LIKE YOU'RE
11:50AM 8 NOT DOING THAT.

11:50AM 9 MS. VOLKAR: THAT'S NOT OUR INTENTION, YOUR HONOR.

11:50AM 10 AGAIN, BECAUSE WE BELIEVE THAT HE'S TESTIFYING ABOUT WHAT
11:50AM 11 HE OBSERVED IN HIS ROLE AS LAB DIRECTOR. WE BELIEVE THAT HE'S
11:50AM 12 TESTIFIED ABOUT THINGS THAT HE WITNESSED AND PARTICIPATED IN IN
11:50AM 13 THE ROLE THAT HE WAS HIRED FOR BY MS. HOLMES TO DO AT THERANOS,
11:50AM 14 AND SO BECAUSE OF THAT HE CAN CERTAINLY DO THAT WITHOUT
11:50AM 15 REFERENCE TO, FOR EXAMPLE, THE SIGMA METRICS.

11:50AM 16 THE COURT: RIGHT.

11:50AM 17 MS. VOLKAR: AGAIN, THE SIGMA METRICS WAS ONE OF
11:50AM 18 MULTIPLE TYPES OF ANALYSES HE RAN IN ORDER TO ANSWER THE
11:50AM 19 QUESTIONS THAT MS. HOLMES AND OTHERS AT THE COMPANY WANTED TO
11:50AM 20 KNOW WHICH WAS IN CONNECTION WITH THE CMS INSPECTION.

11:50AM 21 AND HE USED THE SIGMA METRIC IN PART BECAUSE HE THOUGHT IT
11:50AM 22 WAS ONE OF THE EASIEST WAYS TO EXPLAIN IT BECAUSE IT ULTIMATELY
11:50AM 23 RESULTS IN ONE NUMBER.

11:50AM 24 THE COURT: THAT'S WHAT HE USED AS A TOOL TO CONVEY
11:50AM 25 THE INFORMATION. I UNDERSTAND THAT.

11:50AM 1 AND HE MAY BE -- YOU'VE HEARD ME. I THINK I HAVE SOME
11:50AM 2 CONCERNS WITH THAT IF HE'S NOT GOING TO BE AN EXPERT.

11:50AM 3 MS. VOLKAR: UH-HUH.

11:50AM 4 THE COURT: AND THAT'S A HEADS UP TO YOU HOW YOU
11:51AM 5 WANT TO FASHION YOUR EXAMINATION IF HE'S NOT AN EXPERT.

11:51AM 6 MS. VOLKAR: YES.

11:51AM 7 THE COURT: AND, MR. WADE, I'M NOT INCLINED TODAY TO
11:51AM 8 GIVE 20 PERCENT LIMITATION ON TESTIMONY BECAUSE WE DON'T KNOW
11:51AM 9 WHAT THAT IS YET. BASED ON MS. VOLKAR'S REPRESENTATION HERE, I
11:51AM 10 DON'T THINK IT'S APPROPRIATE FOR ME TO WHOLESALE LIMIT ANYTHING
11:51AM 11 NOW.

11:51AM 12 I THINK I'VE SHARED WITH YOU MY CONCERNS. I ASKED ABOUT
11:51AM 13 RULE 16. I WAS CONCERNED ABOUT THAT AS AN EXPERT NOTICE.

11:51AM 14 WHAT I UNDERSTAND NOW IS, ALTHOUGH MS. VOLKAR BELIEVES
11:51AM 15 THERE'S NO RULE 16 VIOLATION SHE BELIEVES SHE CAN, IF NEEDED,
11:51AM 16 ENGAGE A DAUBERT OR OTHERWISE QUALIFY THIS WITNESS AS AN
11:51AM 17 EXPERT, BUT WHAT I HEAR HER TELLING US TODAY IS THIS WITNESS IS
11:51AM 18 GOING TO BE CALLED AS A PERCIPIENT WITNESS.

11:51AM 19 THE QUESTION OF WHETHER OR NOT THAT TESTIMONY LEAVES THE
11:51AM 20 PUBLIC ARENA, IF YOU WILL, OR CALLS UPON EXPERTISE FOR ITS
11:52AM 21 FOUNDATION IS ONE THAT WE'LL JUST HAVE TO WAIT AND SEE.

11:52AM 22 I'VE GIVEN YOU -- I DON'T WANT TO CALL IT AN ADMONITION,
11:52AM 23 BUT I'VE GIVEN YOU MY CONCERNS. LET ME PUT IT THAT WAY.

11:52AM 24 MS. VOLKAR: YOUR HONOR, IF I MAY JUST FOLLOW UP
11:52AM 25 WITH ONE MORE POINT RELATED TO DR. ROSENDORFF IN THE COURT'S

11:52AM 1 MOTION IN LIMINE ORDER, WHEN DISCUSSING WHETHER OR NOT HE CAN
11:52AM 2 TALK ABOUT VIOLATIONS OF INDUSTRY STANDARD AND GOVERNMENT
11:52AM 3 REGULATIONS AND THOSE TYPES OF THINGS, I THINK ALONG A SIMILAR
11:52AM 4 VEIN HERE, THIS COURT HELD THAT HE COULD ABSOLUTELY TALK ABOUT
11:52AM 5 SUCH ITEMS WHEN EVALUATING MS. HOLMES'S INTENT IN THE ALLEGED
11:52AM 6 SCHEME TO DEFRAUD.

11:52AM 7 SO WE JUST WANTED TO PUT FORTH THAT OF COURSE THERE'S
11:52AM 8 ANOTHER ASPECT AS TO WHY ALL OF THIS IS RELEVANT AND PERTINENT
11:52AM 9 AND PERCIPIENT TESTIMONY.

11:52AM 10 THE COURT: OKAY. THANK YOU.

11:52AM 11 MR. WADE: YOUR HONOR, A COUPLE OF MORE POINTS, AND
11:52AM 12 MAYBE THIS IS AN EFFORT TO TRY TO SEEK CLARITY HERE BECAUSE I
11:52AM 13 STILL -- I DON'T -- FIRST OF ALL, DR. ROSENDORFF IS A DISCLOSED
11:52AM 14 EXPERT, OKAY? SO WE KNEW HE WAS GOING TO BE AN EXPERT, IT WAS
11:52AM 15 TIMELY, AND THE LITIGATION PROCEEDED WITH THE BENEFIT OF THAT.

11:52AM 16 SECOND, I HAVE HEARD COUNSEL SAY THEY BELIEVE THAT THEY
11:53AM 17 CAN OFFER EVERYTHING THAT THEY'VE IDENTIFIED AS PERCIPIENT
11:53AM 18 WITNESS TESTIMONY, AND THEY'RE NOT GOING TO DO A RULE 16
11:53AM 19 DISCLOSURE.

11:53AM 20 BUT RESPECTFULLY, YOUR HONOR, IT'S PLAIN FROM THE RECORD
11:53AM 21 BEFORE THE COURT THAT THAT IS NOT THE CASE. SO KICKING THIS
11:53AM 22 CAN DOWN THE ROAD AND SAYING WE DON'T NEED TO GET DISCLOSURE
11:53AM 23 HERE IS CREATING A SERIOUS RISK OF THE NEED FOR A CONTINUANCE
11:53AM 24 DOWN THE ROAD BECAUSE I'M NOT EXACTLY SURE WHAT IT IS THAT
11:53AM 25 WE'RE SUPPOSED TO DO HERE.

11:53AM 1 AM I SUPPOSED TO PREPARE TO EXAMINE HIM AS A WITNESS
11:53AM 2 BECAUSE NOW I'M, QUOTE-UNQUOTE, "ON NOTICE OF HIS EXPERT
11:53AM 3 TESTIMONY"? BECAUSE THAT NOTICE IS DEFICIENT.

11:53AM 4 AND SO IF -- AND IT'S NOT NECESSARILY CURABLE JUST THROUGH
11:53AM 5 A DAUBERT HEARING. THERE WOULD BE ADDITIONAL BACK WORK THAT
11:53AM 6 WOULD NEED TO BE DONE. SO I HAVE SOME SERIOUS CONCERNS ABOUT
11:54AM 7 JUST KICKING THIS CAN DOWN THE ROAD.

11:54AM 8 I WANT TO BE CLEAR, I THINK A LOT OF THESE ISSUES ARE
11:54AM 9 EXPERT WITNESSES -- EXPERT ISSUES, AND IF WE DEFER THEM, IT'S
11:54AM 10 CREATING RISK FOR THE COURT.

11:54AM 11 THE COURT: WELL, I APPRECIATE YOU LOOKING OUT FOR
11:54AM 12 THE COURT. I ALWAYS DO.

11:54AM 13 MR. WADE: IT'S GREAT RISK FOR ALL OF US,
11:54AM 14 YOUR HONOR, BECAUSE I THINK WE ALL WANT TO PROCEED AS QUICKLY
11:54AM 15 AS WE CAN.

11:54AM 16 THE COURT: WE ALL DO, WE WANT TO PROCEED AS
11:54AM 17 EFFICIENTLY AS WE CAN AND ALSO RESPECTING EVERYONE'S INTERESTS
11:54AM 18 AND RIGHTS IN THE CASE.

11:54AM 19 I HOPE I SHARED WITH YOU MY CONCERNS ABOUT THE RULE 16. I
11:54AM 20 DON'T KNOW IF I COULD BE ANY MORE TRANSPARENT THAN TO TELL YOU
11:54AM 21 THAT.

11:54AM 22 WHAT I ALSO HEARD IS THAT THIS WITNESS IS GOING TO BE --
11:54AM 23 IS NOT CALLED AS AN EXPERT, BUT HE WILL BE CALLED AS A
11:54AM 24 PERCIPIENT WITNESS.

11:54AM 25 AND WE ALL KNOW IN LITIGATION EVERYONE PROCEEDS AT THEIR

11:54AM 1 OWN PERIL. IF A WITNESS IS CALLED AND IF THERE'S A DIVERSION
11:54AM 2 FROM WHAT THE COURT BELIEVES IS APPROPRIATE TESTIMONY, I'M SURE
11:54AM 3 I'LL HEAR ABOUT IT.

11:55AM 4 THERE WAS A MOTION ASKING ME TO SO ADVISE THE JURY IN SOME
11:55AM 5 PRELIMINARY INSTRUCTIONS, IF I RECALL CORRECTLY, BUT -- SO
11:55AM 6 THAT'S -- THANK YOU FOR THE HELP HERE. I DON'T WANT TO BE COY
11:55AM 7 HERE, BUT I WAS CONCERNED ABOUT RULE 16. I THINK I'VE GOT
11:55AM 8 INFORMATION ABOUT THAT.

11:55AM 9 MY NEXT CONCERN WAS WHAT IS THIS WITNESS, PERCIPIENT OR
11:55AM 10 EXPERT?

11:55AM 11 IT SOUNDS LIKE MS. VOLKAR'S ARGUMENT IS THAT HE COULD BE
11:55AM 12 EITHER, HE COULD BE BOTH, BUT FOR TODAY'S PURPOSE, JUDGE, WE'RE
11:55AM 13 GOING TO CALL HIM AS A PERCIPIENT WITNESS, AND HE'S GOING TO
11:55AM 14 TESTIFY AS SUCH.

11:55AM 15 I'VE SHARED WITH YOU MY CONCERNS ABOUT THE SIGMA 6, AND I
11:55AM 16 DO THINK THAT THAT GOES BEYOND THE EVERY DAY LIFE EXPERIENCES
11:55AM 17 OF THE JURY, AND YOU CAN TAKE THAT CAUTION FOR WHAT IT IS AND
11:55AM 18 WHAT IT IS WORTH.

11:55AM 19 BUT THERE ARE OTHER AVENUES, AND WE ALL AGREE THAT THERE
11:55AM 20 ARE PERCIPIENT WITNESSES THAT CAN TESTIFY ABOUT THEIR JOBS,
11:55AM 21 ABOUT WHAT THEY DO, WHAT THEIR JOB TITLE ENCOMPASSES, AND WHAT
11:56AM 22 THEIR JOB DUTIES ARE, AND THOSE DON'T NECESSARILY GO INTO AN
11:56AM 23 EXPERTISE TYPE OF ANALYSIS. IT'S WHAT THEY DO. IT'S THE
11:56AM 24 INFORMATION THAT THEY GATHER WITHOUT ANY ANALYTICS. IT'S WHAT
11:56AM 25 THEY DO.

11:56AM 1 MR. WADE, WHEN YOU GO BACK TO SCHOOL FOR YOUR KIDS AND
11:56AM 2 THEY SAY WHAT DOES A LAWYER DO?

11:56AM 3 WELL, I OBJECT BECAUSE I HAVE A DUTY TO OBJECT I'M
11:56AM 4 INFORMED.

11:56AM 5 WELL, WHAT DO YOU DO?

11:56AM 6 WELL, I OBJECT ABOUT RULE 805.

11:56AM 7 WELL, WHAT IS RULE 805?

11:56AM 8 AND THEN IF YOU START GETTING INTO A DISCOURSE WITH THESE
11:56AM 9 FIFTH GRADERS, THEN IT BECOMES EXPERTISE. IF YOU SAY, WELL,
11:56AM 10 IT'S JUST SOMETHING THAT WE DO AND YOU CAN'T SAY WHAT IS
11:56AM 11 OUTSIDE OF THE COURT, THAT'S FAIR ENOUGH, THAT'S THE
11:56AM 12 DESCRIPTION.

11:56AM 13 SO LET ME JUST LEAVE IT WITH THAT. THANK YOU FOR YOUR
11:56AM 14 HELP. HAVE A GOOD WEEKEND, EVERYONE. BE SAFE.

11:56AM 15 WE'LL PROBABLY -- ARE WE GOING TO GET TOGETHER NEXT WEEK
11:56AM 16 SOME TIME? I THINK WE NEED TO GET TOGETHER TO TALK ABOUT JURY
11:57AM 17 SELECTION ISSUES.

11:57AM 18 MR. WADE: WE'LL BE CONFERRING WITH THE GOVERNMENT,
11:57AM 19 AND WE'LL BE IN TOUCH WITH THE COURT.

11:57AM 20 HAVE WE WORKED OUT THE TIMING? I THINK MONDAY THE NEXT
11:57AM 21 BATCH OF MATERIALS WILL COME BACK TO THE COURT GIVEN THE COURT
11:57AM 22 IS NOT AVAILABLE ON THE WEEKEND BUT WE'VE BEEN SHARING WITH THE
11:57AM 23 GOVERNMENT ON A TIMELY BASIS.

11:57AM 24 THE COURT: GREAT. TERRIFIC. AND WE'LL HAVE TIME
11:57AM 25 NEXT WEEK TO MEET REGARDING ANY JURY SELECTION ISSUES THAT HAVE

11:57AM 1 NOT YET BEEN RESOLVED.

11:57AM 2 MR. WADE: GOOD.

11:57AM 3 MR. LEACH: AND, YOUR HONOR, WE DO HAVE THE HEARING
11:57AM 4 ON THURSDAY AS WELL.

11:57AM 5 THE COURT: WE DO. SO WE'LL BE TOGETHER ON THAT
11:57AM 6 DATE AS WELL.

11:57AM 7 MS. VOLKAR: YES. THANK YOU, YOUR HONOR.

11:57AM 8 THE CLERK: COURT IS ADJOURNED.

11:57AM 9 (COURT CONCLUDED AT 11:57 A.M.)

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CERTIFICATE OF REPORTER

I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

A handwritten signature in black ink that reads "Irene Rodriguez". The signature is written in a cursive, flowing style with a large, decorative flourish at the end of the last name.

IRENE RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074

DATED: AUGUST 23, 2021